# Clinical trial results:
# A phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and Immunogenicity and Phase 2/3 Placebo-Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-COV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children

## Summary

| | |
|---|---|
| EudraCT number | 2020-005442-42 |
| Trial protocol | FI PL |
| Global end of trial date | 08 December 2023 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 21 June 2024 |
| First version publication date | 21 June 2024 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | C4591007 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT04816643 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | BioNTech SE |
| Sponsor organisation address | An der Goldgrube 12, Mainz, Germany, 55131 |
| Public contact | BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de |
| Scientific contact | BioNTech clinical trials patient information, BioNTech SE, +49 6131 90840, patients@biontech.de |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMEA-002861-PIP02-20 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 05 January 2024 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 08 December 2023 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

Phase 1: To describe the safety and tolerability profiles of prophylactic BNT162b2 at each dose level in each age group.
Phase 2/3: To define the safety profile of prophylactic BNT162b2 in all participants (selected-dose and obtaining-serum-samples-for potential- troponin I-testing portions of the study) in each age group. To immunobridge the immune response elicited by prophylactic BNT162b2 between Phase 2/3 participants at the dose selected in each age group and participants 16 to 25 years of age from the C4591001 study without serological or virological evidence (up to 1 month after receipt of Dose 2) of past SARS-CoV-2 infection. To immunobridge the immune response elicited by prophylactic BNT162b2 between Phase 2/3 participants at the dose selected in each age group and participants 16 to 25 years of age from the C4591001 study without serological or virological evidence (up to 1 month after receipt of Dose 3) of past SARS-CoV-2 infection.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 24 March 2021 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | United States: 9608 |
| Country: Number of subjects enrolled | Mexico: 353 |
| Country: Number of subjects enrolled | Spain: 413 |
| Country: Number of subjects enrolled | Brazil: 262 |
| Country: Number of subjects enrolled | Finland: 414 |
| Country: Number of subjects enrolled | Poland: 691 |
| Worldwide total number of subjects | 11741 |
| EEA total number of subjects | 1518 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |

| | |
|---|---|
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 2192 |
| Children (2-11 years) | 9062 |
| Adolescents (12-17 years) | 487 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

The study consisted of 2 parts, Phase 1 and Phase 2/3. The overall baseline period presented below was created to support display of the demographic characteristics for all study phases. The complete disposition information is presented below in separate tables for each individual phase, respectively.

### Pre-assignment

Screening details:

Out of 11837 participants enrolled, 11836 were randomized. However, one participant was enrolled in error and assigned to treatment, of which 11741 were vaccinated.

### Period 1

| | |
|---|---|
| Period 1 title | Baseline Period |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age |

Arm description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age |

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |

| | |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 2 doses of 20 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: 5 to <12 Years 30/30 mcg |
|---|---|

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 2 doses of 30 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: 5 to <12 Years 30/10 mcg |
|---|---|

Arm description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third

dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age |

Arm description:

Participants aged 6 months to <2 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 2/3: Placebo: 6 months to <2 years of age |

Arm description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

| | |
|---|---|
| **Arm title** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age |

Arm description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 2/3: Placebo: 2 to <5 years of age |

Arm description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

| | |
|---|---|
| **Arm title** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age |

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 2/3: Placebo: 5 to <12 years of age |

Arm description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

| | |
|---|---|
| **Arm title** | Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age |

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 2/3: Troponin group: Placebo: 5 to <12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Arm type | Placebo |
|---|---|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

| **Arm title** | Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age |
|---|---|

Arm description:

Participants aged 12 to <16 years received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 30 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Number of subjects in period 1** | Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |
|---|---|---|---|
| Started | 16 | 16 | 32 |
| Completed | 16 | 16 | 32 |

| **Number of subjects in period 1** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1: 5 to <12 Years 30/30 mcg |
|---|---|---|---|
| Started | 16 | 16 | 4 |
| Completed | 16 | 16 | 4 |

| **Number of subjects in period 1** | Phase 1: 5 to <12 Years 30/10 mcg | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years of age |
|---|---|---|---|
| Started | 12 | 1458 | 718 |
| Completed | 12 | 1458 | 718 |

| **Number of subjects in period 1** | Phase 2/3: BNT162b2 (3 mcg): | Phase 2/3: Placebo: 2 to <5 years of age | Phase 2/3: BNT162b2 (10 |
|---|---|---|---|

| | 2 to <5 years of age | | mcg): 5 to <12 years of age |
|---|---|---|---|
| Started | 2368 | 1173 | 3109 |
| Completed | 2368 | 1173 | 3109 |

| **Number of subjects in period 1** | Phase 2/3: Placebo: 5 to <12 years of age | Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age | Phase 2/3: Troponin group: Placebo: 5 to <12 years of age |
|---|---|---|---|
| Started | 1538 | 518 | 260 |
| Completed | 1538 | 518 | 260 |

| **Number of subjects in period 1** | Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age |
|---|---|
| Started | 487 |
| Completed | 487 |

## Period 2

| Period 2 title | Phase 1 |
|---|---|
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

## Arms

| Are arms mutually exclusive? | Yes |
|---|---|
| **Arm title** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age |

Arm description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age |
|---|---|

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Arm type | Experimental |
|---|---|

| | |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |
|---|---|

Arm description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 2 doses of 20 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2

approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 2 doses of 30 mcg and 1 dose of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |

Arm description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Number of subjects in period 2[1]** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |
|---|---|---|---|
| Started | 16 | 16 | 32 |
| Completed | 8 | 7 | 14 |
| Not completed | 8 | 9 | 18 |
| Withdrawal by parent/guardian/subject | 1 | 3 | 4 |
| Unspecified | 6 | 3 | 4 |
| Lost to follow-up | - | 1 | 2 |
| Protocol deviation | 1 | 2 | 8 |

| **Number of subjects in period 2[1]** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age |
|---|---|---|---|
| Started | 16 | 16 | 4 |
| Completed | 2 | 3 | 2 |
| Not completed | 14 | 13 | 2 |
| Withdrawal by parent/guardian/subject | 1 | 2 | - |
| Unspecified | 8 | 2 | 1 |
| Lost to follow-up | - | - | - |
| Protocol deviation | 5 | 9 | 1 |

| Number of subjects in period 2[1] | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|
| Started | 12 |
| Completed | 1 |
| Not completed | 11 |
| Withdrawal by parent/guardian/subject | 1 |
| Unspecified | 4 |
| Lost to follow-up | - |
| Protocol deviation | 6 |

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: The participants enrolled in both periods are different.

## Period 3

| | |
|---|---|
| Period 3 title | Phase 2/3 |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

## Arms

| | |
|---|---|
| Are arms mutually exclusive? | No |
| **Arm title** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age |

Arm description:

Participants aged 6 months to <2 years were randomized to received 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| | |
|---|---|
| **Arm title** | Phase 2/3: Placebo: 6 months to <2 years |

Arm description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly.

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly.

| **Arm title** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age |
|---|---|

Arm description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 3 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 2/3: Placebo: 2 to <5 years of age |
|---|---|

Arm description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Arm type | Placebo |
|---|---|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

| **Arm title** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 2/3: Placebo: 5 to <12 years of age |
|---|---|

Arm description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Arm type | Placebo |
|---|---|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered

intramuscularly separated by 21 days interval as part of this study.

| **Arm title** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years |
|---|---|

Arm description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 10 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| **Arm title** | Phase 2/3:Troponin group:Placebo:5 to <12 years |
|---|---|

Arm description:

Participants aged  5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Arm type | Placebo |
|---|---|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received normal saline (0.9% sodium chloride solution for injection) administered intramuscularly separated by 21 days interval as part of this study.

| **Arm title** | Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years |
|---|---|

Arm description:

Participants aged 12 to <16 years were received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

| Arm type | Experimental |
|---|---|
| Investigational medicinal product name | BNT162b2 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received 3 doses of 30 mcg BNT162b2 RNA-LNP vaccine utilizing modRNA (100 microgram/milliliter) administered intramuscularly.

| Number of subjects in period 3 | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age |
|---|---|---|---|
| Started | 1458 | 718 | 2368 |
| Completed | 712 | 261 | 1215 |
| Not completed | 746 | 457 | 1153 |
| Withdrawal by parent/guardian/subject | 199 | 196 | 427 |
| Physician decision | 3 | 1 | 2 |
| Refused further study procedures | - | - | - |
| Pregnancy | - | - | - |
| Adverse event | 1 | - | 3 |
| Unspecified | 465 | 221 | 464 |
| Lost to follow-up | 53 | 23 | 109 |
| Protocol deviation | 25 | 16 | 148 |

| Number of subjects in period 3 | Phase 2/3: Placebo: 2 to <5 years of age | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age |
|---|---|---|---|
| Started | 1173 | 3109 | 1538 |
| Completed | 406 | 1604 | 636 |
| Not completed | 767 | 1505 | 902 |
| Withdrawal by parent/guardian/subject | 458 | 816 | 543 |
| Physician decision | 1 | - | - |
| Refused further study procedures | - | 2 | - |
| Pregnancy | - | - | - |
| Adverse event | - | - | - |
| Unspecified | 171 | 86 | 47 |
| Lost to follow-up | 55 | 126 | 41 |
| Protocol deviation | 82 | 475 | 271 |

| Number of subjects in period 3 | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo:5 to <12 years | Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years |
|---|---|---|---|
| Started | 518 | 260 | 487 |
| Completed | 395 | 188 | 424 |
| Not completed | 123 | 72 | 63 |
| Withdrawal by parent/guardian/subject | 66 | 37 | 40 |
| Physician decision | 1 | 1 | - |
| Refused further study procedures | - | - | - |
| Pregnancy | - | - | 2 |
| Adverse event | - | - | - |
| Unspecified | 11 | 4 | - |

| | | | |
|---|---|---|---|
| Lost to follow-up | 14 | 10 | 15 |
| Protocol deviation | 31 | 20 | 6 |

## Baseline characteristics

### Reporting groups

| Reporting group title | Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age |
|---|---|

Reporting group description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 1: 5 to <12 Years 30/30 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 1: 5 to <12 Years 30/10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1  and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age |
|---|---|

Reporting group description:

Participants aged 6 months to <2 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 2/3: Placebo: 6 months to <2 years of age |
|---|---|

Reporting group description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 2/3: Placebo: 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3: Placebo: 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3: Troponin group: Placebo: 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age |
|---|---|

Reporting group description:

Participants aged 12 to <16 years received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

| **Reporting group values** | Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |
|---|---|---|---|
| Number of subjects | 16 | 16 | 32 |
| Age Categorical<br>Units: Participants | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 16 | 0 | 0 |
| Children (2-11 years) | 0 | 16 | 32 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Gender Categorical<br>Units: Participants | | | |
| Female | 6 | 7 | 13 |
| Male | 10 | 9 | 19 |
| Race<br>Units: Subjects | | | |
| White | 13 | 12 | 25 |
| Black or African American | 0 | 0 | 2 |
| Asian | 1 | 1 | 2 |
| Multiracial | 2 | 3 | 2 |
| American Indian or Alaska Native | 0 | 0 | 1 |
| Native Hawaiian or other Pacific Islander | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Not reported | 0 | 0 | 0 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic/Latino | 3 | 0 | 1 |
| Non-Hispanic/non-Latino | 13 | 16 | 31 |
| Not reported | 0 | 0 | 0 |

| **Reporting group values** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1: 5 to <12 Years 30/30 mcg |
|---|---|---|---|
| Number of subjects | 16 | 16 | 4 |
| Age Categorical<br>Units: Participants | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 16 | 16 | 4 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Gender Categorical<br>Units: Participants | | | |
| Female | 11 | 6 | 1 |
| Male | 5 | 10 | 3 |
| Race<br>Units: Subjects | | | |
| White | 11 | 13 | 4 |
| Black or African American | 3 | 0 | 0 |
| Asian | 2 | 2 | 0 |
| Multiracial | 0 | 1 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or other Pacific Islander | 0 | 0 | 0 |
| Not reported | 0 | 0 | 0 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic/Latino | 2 | 0 | 2 |
| Non-Hispanic/non-Latino | 14 | 16 | 2 |
| Not reported | 0 | 0 | 0 |

| **Reporting group values** | Phase 1: 5 to <12 Years 30/10 mcg | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years of age |
|---|---|---|---|
| Number of subjects | 12 | 1458 | 718 |
| Age Categorical<br>Units: Participants | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Infants and toddlers (28 days-23 months) | 0 | 1458 | 718 |
| Children (2-11 years) | 12 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Gender Categorical<br>Units: Participants | | | |
| Female | 6 | 728 | 372 |
| Male | 6 | 730 | 346 |
| Race<br>Units: Subjects | | | |
| White | 10 | 1126 | 562 |
| Black or African American | 0 | 73 | 34 |
| Asian | 1 | 101 | 51 |
| Multiracial | 1 | 149 | 65 |
| American Indian or Alaska Native | 0 | 4 | 1 |
| Native Hawaiian or other Pacific Islander | 0 | 0 | 0 |
| Not reported | 0 | 5 | 5 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic/Latino | 0 | 248 | 93 |
| Non-Hispanic/non-Latino | 12 | 1205 | 620 |
| Not reported | 0 | 5 | 5 |

| **Reporting group values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|---|---|
| Number of subjects | 2368 | 1173 | 3109 |
| Age Categorical<br>Units: Participants | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 2368 | 1173 | 3109 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Gender Categorical<br>Units: Participants | | | |
| Female | 1197 | 570 | 1500 |
| Male | 1171 | 603 | 1609 |
| Race<br>Units: Subjects | | | |
| White | 1870 | 913 | 2404 |
| Black or African American | 138 | 71 | 179 |
| Asian | 147 | 92 | 256 |

| | | | |
|---|---|---|---|
| Multiracial | 189 | 86 | 235 |
| American Indian or Alaska Native | 4 | 4 | 13 |
| Native Hawaiian or other Pacific Islander | 2 | 1 | 10 |
| Not reported | 18 | 6 | 12 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic/Latino | 426 | 193 | 526 |
| Non-Hispanic/non-Latino | 1934 | 979 | 2579 |
| Not reported | 8 | 1 | 4 |

| **Reporting group values** | Phase 2/3: Placebo: 5 to <12 years of age | Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age | Phase 2/3: Troponin group: Placebo: 5 to <12 years of age |
|---|---|---|---|
| Number of subjects | 1538 | 518 | 260 |
| Age Categorical<br>Units: Participants | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 1538 | 518 | 260 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Gender Categorical<br>Units: Participants | | | |
| Female | 759 | 252 | 120 |
| Male | 779 | 266 | 140 |
| Race<br>Units: Subjects | | | |
| White | 1199 | 425 | 219 |
| Black or African American | 101 | 19 | 11 |
| Asian | 118 | 49 | 16 |
| Multiracial | 106 | 23 | 13 |
| American Indian or Alaska Native | 4 | 1 | 1 |
| Native Hawaiian or other Pacific Islander | 0 | 0 | 0 |
| Not reported | 10 | 1 | 0 |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic/Latino | 265 | 52 | 34 |
| Non-Hispanic/non-Latino | 1273 | 466 | 226 |
| Not reported | 0 | 0 | 0 |

| **Reporting group values** | Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age | Total | |
|---|---|---|---|
| Number of subjects | 487 | 11741 | |

| | | | |
|---|---|---|---|
| Age Categorical<br>Units: Participants | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 2192 | |
| Children (2-11 years) | 0 | 9062 | |
| Adolescents (12-17 years) | 487 | 487 | |
| Adults (18-64 years) | 0 | 0 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Gender Categorical<br>Units: Participants | | | |
| Female | 216 | 5764 | |
| Male | 271 | 5977 | |
| Race<br>Units: Subjects | | | |
| White | 228 | 9034 | |
| Black or African American | 40 | 671 | |
| Asian | 4 | 843 | |
| Multiracial | 1 | 876 | |
| American Indian or Alaska Native | 209 | 242 | |
| Native Hawaiian or other Pacific Islander | 0 | 13 | |
| Not reported | 5 | 62 | |
| Ethnicity<br>Units: Subjects | | | |
| Hispanic/Latino | 422 | 2267 | |
| Non-Hispanic/non-Latino | 65 | 9451 | |
| Not reported | 0 | 23 | |

## End points

### End points reporting groups

| Reporting group title | Phase 1:BNT162b2 (3 mcg):6 Months to < 2 years of age |
|---|---|
| Reporting group description: | |
| Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2. | |
| Reporting group title | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age |
| Reporting group description: | |
| Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2. | |
| Reporting group title | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |
| Reporting group description: | |
| Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2. | |
| Reporting group title | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age |
| Reporting group description: | |
| Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2. | |
| Reporting group title | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age |
| Reporting group description: | |
| Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2. | |
| Reporting group title | Phase 1: 5 to <12 Years 30/30 mcg |
| Reporting group description: | |
| Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2. | |
| Reporting group title | Phase 1: 5 to <12 Years 30/10 mcg |
| Reporting group description: | |
| Participants aged 5 to <12 years of age received 30 mcg in dose 1 and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2. | |
| Reporting group title | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age |
| Reporting group description: | |
| Participants aged 6 months to <2 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2. | |
| Reporting group title | Phase 2/3: Placebo: 6 months to <2 years of age |
| Reporting group description: | |
| Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study. | |
| Reporting group title | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age |
| Reporting group description: | |
| Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2. | |
| Reporting group title | Phase 2/3: Placebo: 2 to <5 years of age |
| Reporting group description: | |
| Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study. | |

| Reporting group title | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3: Placebo: 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3:Troponin group:BNT162b2(10 mcg):5 to<12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3: Troponin group: Placebo: 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged  5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3:Troponin group:BNT162b2(30 mcg):12 to<16years of age |
|---|---|

Reporting group description:

Participants aged 12 to <16 years received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age |
|---|---|

Reporting group description:

Participants aged 6 months to less than (<) 2 years of age received 2 doses of 3 microgram (mcg) BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 3 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 10 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 20 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 2 doses of 30 mcg BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years of age received 30 mcg in dose 1  and 10 mcg in dose 2 of BNT162b2 vaccine intramuscularly separated by 21 days interval as part of this study. Participants received third

dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age |
|---|---|

Reporting group description:

Participants aged 6 months to <2 years were randomized to received 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 2/3: Placebo: 6 months to <2 years |
|---|---|

Reporting group description:

Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly.

| Reporting group title | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 2 doses of 3 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 3 mcg BNT162b2 approximately 60 days after vaccination 2.

| Reporting group title | Phase 2/3: Placebo: 2 to <5 years of age |
|---|---|

Reporting group description:

Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3: Placebo: 5 to <12 years of age |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 10 mcg BNT162b2 approximately 175 days after vaccination 2.

| Reporting group title | Phase 2/3:Troponin group:Placebo:5 to <12 years |
|---|---|

Reporting group description:

Participants aged  5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly separated by 21 days interval as part of this study.

| Reporting group title | Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years |
|---|---|

Reporting group description:

Participants aged 12 to <16 years were received 2 doses of 10 mcg BNT162b2 intramuscularly separated by 21 days interval as part of this study. Participants received third dose of 30 mcg BNT162b2 approximately 175 days after vaccination 2.

| Subject analysis set title | Phase 1: 5 to <12 Years BNT162b2 10 mcg |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants aged 5 to <12 years who received the third dose of 10 mcg BNT162b2 as part of this study were included.

| Subject analysis set title | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants aged 16 to 25 years from study C4591001 (NCT04816643) who received 2 doses of original BNT162b2 30 mcg were included.

| Subject analysis set title | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg) |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants aged 2 to <5 years at the time of receiving third dose received 3 mcg BNT162b2intramuscularly as part of this study.

| Subject analysis set title | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg) |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants in the 2 to < 5years of age group who aged up to 5 years at the time of the 3rd dose received the age-appropriate dose of 10 mcg BNT162b2 intramuscularly.

| Subject analysis set title | Phase 2/3: BNT162b2 (10 mcg) 3-Dose Set |
|---|---|
| Subject analysis set type | Sub-group analysis |

Subject analysis set description:

Participants aged 5 to <12 years who received Dose 3 and completed 1 month post-Dose 3 visit in the Dose 3 evaluable immunogenicity population without evidence of prior infection up 1 month post-Dose 3 were included.

| Subject analysis set title | Phase 2/3: BNT162b2 30 mcg 16-25 Years |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants aged >=12 to <16 years who received 3 doses of original BNT162b2 30 mcg were included.

| Subject analysis set title | Phase 2/3: C4591001: Placebo 16-25 Years |
|---|---|
| Subject analysis set type | Per protocol |

Subject analysis set description:

Participants aged >=12 to <16 years who received placebo in Phase 2/3 were included.

| Subject analysis set title | Ph2/3:BNT162b2 3mcg:6M-<5Y:WoEI:evaluable efficacy(3dose)set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Phase 2/3 (Ph2/3):Participants aged >=6 months to <5 years (6M-<5Y) in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period without evidence of infection(WoEI) prior to 7 days after Dose 3.

| Subject analysis set title | Phase2/3:Placebo:6M-<5Y):WoEI:evaluable efficacy(3-dose)set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Participants aged >=6 months to <5 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period without evidence of infection prior to 7 days after Dose 3.

| Subject analysis set title | Phase 2/3:BNT162b2 3 mcg 6M<5Y:evaluable efficacy(3-dose)set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Participants aged >=6 months to <5 years in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

| Subject analysis set title | Phase 2/3:Placebo 6M-<5Y:evaluable efficacy(3-dose)set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Participants aged >=6 months to <5 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

| Subject analysis set title | Ph2/3:BNT162b2 3 mcg 5-<12Y:WoEI:evaluable efficacy(3-dose)set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Phase 2/3(Ph2/3):Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period without evidence of infection (WoEI)prior to 7 days after Dose 3.

| Subject analysis set title | Phase 2/3:Placebo 5 to <12Y:WoEI:evaluable efficacy(3-dose)set |
|---|---|

| Subject analysis set type | Full analysis |
|---|---|

Subject analysis set description:

Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period without evidence of infection prior to 7 days after Dose 3.

| Subject analysis set title | Phase 2/3:BNT162b2 3 mcg 5-<12Y:evaluable efficacy(3-dose)set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of original BNT162b2 3 mcg during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

| Subject analysis set title | Phase 2/3:Placebo 5-<12Y:evaluable efficacy(3-dose)set |
|---|---|
| Subject analysis set type | Full analysis |

Subject analysis set description:

Participants aged 5 to <12 years in evaluable efficacy (3-Dose) population who received 3 doses of placebo during the blinded follow up period with and without evidence of infection prior to 7 days after Dose 3.

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age[1] |
|---|---|

End point description:

Local reactions were collected in electronic diary (e-diary) or during unscheduled clinical assessments from Day 1 to 7 after Dose 1. Redness and swelling were measured and recorded in measuring device unit (mdu) where, 1 mdu =0.5 centimeter(cm) & were graded as mild(>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe(>7.0 cm)& Grade 4 (G4) (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity) & G4 Emergency room (ER) visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% Confidence interval was based on Clopper and Pearson method. Safety population consisted of all participants who received at least 1 dose of study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 16 | 16 | 4 | 12 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 12.5 (1.6 to 38.3) | 0 (0.0 to 20.6) | 100.0 (39.8 to 100.0) | 16.7 (2.1 to 48.4) |
| Redness: Mild | 6.3 (0.2 to 30.2) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| Redness: Moderate | 6.3 (0.2 to 30.2) | 0 (0.0 to 20.6) | 75.0 (19.4 to 99.4) | 16.7 (2.1 to 48.4) |
| Redness: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Redness: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |

| | | | | |
|---|---|---|---|---|
| Swelling: Any | 18.8 (4.0 to 45.6) | 6.3 (0.2 to 30.2) | 50.0 (6.8 to 93.2) | 8.3 (0.2 to 38.5) |
| Swelling: Mild | 6.3 (0.2 to 30.2) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| Swelling: Moderate | 12.5 (1.6 to 38.3) | 6.3 (0.2 to 30.2) | 25.0 (0.6 to 80.6) | 8.3 (0.2 to 38.5) |
| Swelling: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Swelling: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Pain at the injection site: Any | 87.5 (61.7 to 98.4) | 93.8 (69.8 to 99.8) | 100.0 (39.8 to 100.0) | 83.3 (51.6 to 97.9) |
| Pain at the injection site: Mild | 68.8 (41.3 to 89.0) | 56.3 (29.9 to 80.2) | 50.0 (6.8 to 93.2) | 50.0 (21.1 to 78.9) |
| Pain at the injection site: Moderate | 18.8 (4.0 to 45.6) | 37.5 (15.2 to 64.6) | 50.0 (6.8 to 93.2) | 33.3 (9.9 to 65.1) |
| Pain at the injection site: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Pain at the injection site: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age[2] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 16 | 16 | 4 | 12 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 37.5 (15.2 to 64.6) | 18.8 (4.0 to 45.6) | 75.0 (19.4 to 99.4) | 16.7 (2.1 to 48.4) |
| Redness: Mild | 25.0 (7.3 to 52.4) | 6.3 (0.2 to 30.2) | 25.0 (0.6 to 80.6) | 8.3 (0.2 to 38.5) |

| | | | | |
|---|---|---|---|---|
| Redness: Moderate | 12.5 (1.6 to 38.3) | 12.5 (1.6 to 38.3) | 25.0 (0.6 to 80.6) | 8.3 (0.2 to 38.5) |
| Redness: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| Redness: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Swelling: Any | 31.3 (11.0 to 58.7) | 18.8 (4.0 to 45.6) | 50.0 (6.8 to 93.2) | 0 (0.0 to 26.5) |
| Swelling: Mild | 12.5 (1.6 to 38.3) | 0 (0.0 to 20.6) | 50.0 (6.8 to 93.2) | 0 (0.0 to 26.5) |
| Swelling: Moderate | 18.8 (4.0 to 45.6) | 18.8 (4.0 to 45.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Swelling: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Swelling: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Pain at the injection site: Any | 87.5 (61.7 to 98.4) | 75.0 (47.6 to 92.7) | 100.0 (39.8 to 100.0) | 91.7 (61.5 to 99.8) |
| Pain at the injection site: Mild | 75.0 (47.6 to 92.7) | 50.0 (24.7 to 75.3) | 50.0 (6.8 to 93.2) | 83.3 (51.6 to 97.9) |
| Pain at the injection site: Moderate | 12.5 (1.6 to 38.3) | 25.0 (7.3 to 52.4) | 50.0 (6.8 to 93.2) | 8.3 (0.2 to 38.5) |
| Pain at the injection site: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Pain at the injection site: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age[3] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. All participants aged 5 to <12 years were administered BNT 10 mcg at Dose 3; hence, only BNT 10 mcg arm is reported.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 1: 5 to <12 Years BNT162b2 10 mcg | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 38 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 28.9 (15.4 to 45.9) | | | |
| Redness: Mild | 21.1 (9.6 to 37.3) | | | |
| Redness: Moderate | 7.9 (1.7 to 21.4) | | | |
| Redness: Severe | 0 (0.0 to 9.3) | | | |
| Redness: Grade 4 | 0 (0.0 to 9.3) | | | |
| Swelling: Any | 13.2 (4.4 to 28.1) | | | |
| Swelling: Mild | 10.5 (2.9 to 24.8) | | | |
| Swelling: Moderate | 2.6 (0.1 to 13.8) | | | |
| Swelling: Severe | 0 (0.0 to 9.3) | | | |
| Swelling: Grade 4 | 0 (0.0 to 9.3) | | | |
| Pain at the injection site: Any | 86.8 (71.9 to 95.6) | | | |
| Pain at the injection site: Mild | 68.4 (51.3 to 82.5) | | | |
| Pain at the injection site: Moderate | 18.4 (7.7 to 34.3) | | | |
| Pain at the injection site: Severe | 0 (0.0 to 9.3) | | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 9.3) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age[4] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Fever:oral temperature >= 38.0 degree Celsius (deg C);categorised as Fever:oral temperature >=38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C& >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours(h),moderate:>2 times in 24h,severe:required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events:ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 16 | 16 | 4 | 12 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 deg C | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 33.3 (9.9 to 65.1) |
| Fever:38.0 to 38.4 deg C | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 16.7 (2.1 to 48.4) |
| Fever: >38.4 to 38.9 deg C | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 16.7 (2.1 to 48.4) |
| Fever: >38.9 to 40.0 deg C | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Fever: >40.0 deg C | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Fatigue: Any | 50.0 (24.7 to 75.3) | 68.8 (41.3 to 89.0) | 100.0 (39.8 to 100.0) | 50.0 (21.1 to 78.9) |
| Fatigue: Mild | 37.5 (15.2 to 64.6) | 31.3 (11.0 to 58.7) | 25.0 (0.6 to 80.6) | 16.7 (2.1 to 48.4) |
| Fatigue: Moderate | 12.5 (1.6 to 38.3) | 37.5 (15.2 to 64.6) | 75.0 (19.4 to 99.4) | 33.3 (9.9 to 65.1) |
| Fatigue: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Fatigue: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Headache: Any | 25.0 (7.3 to 52.4) | 31.3 (11.0 to 58.7) | 75.0 (19.4 to 99.4) | 33.3 (9.9 to 65.1) |
| Headache: Mild | 18.8 (4.0 to 45.6) | 31.3 (11.0 to 58.7) | 50.0 (6.8 to 93.2) | 25.0 (5.5 to 57.2) |
| Headache: Moderate | 6.3 (0.2 to 30.2) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 8.3 (0.2 to 38.5) |
| Headache: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Headache: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Chills: Any | 0 (0.0 to 20.6) | 25.0 (7.3 to 52.4) | 50.0 (6.8 to 93.2) | 16.7 (2.1 to 48.4) |
| Chills: Mild | 0 (0.0 to 20.6) | 18.8 (4.0 to 45.6) | 0 (0.0 to 60.2) | 8.3 (0.2 to 38.5) |
| Chills: Moderate | 0 (0.0 to 20.6) | 6.3 (0.2 to 30.2) | 50.0 (6.8 to 93.2) | 8.3 (0.2 to 38.5) |
| Chills: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Chills: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Vomiting: Any | 0 (0.0 to 20.6) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 8.3 (0.2 to 38.5) |
| Vomiting: Mild | 0 (0.0 to 20.6) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 8.3 (0.2 to 38.5) |
| Vomiting: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Vomiting: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Vomiting: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Diarrhea: Any | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Diarrhea: Mild | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Diarrhea: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Diarrhea: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |

| | | | | |
|---|---|---|---|---|
| Diarrhea: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Any | 12.5 (1.6 to 38.3) | 25.0 (7.3 to 52.4) | 100.0 (39.8 to 100.0) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Mild | 6.3 (0.2 to 30.2) | 25.0 (7.3 to 52.4) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Moderate | 6.3 (0.2 to 30.2) | 0 (0.0 to 20.6) | 75.0 (19.4 to 99.4) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened joint pain: Any | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 25.0 (0.6 to 80.6) | 8.3 (0.2 to 38.5) |
| New or worsened joint pain: Mild | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 8.3 (0.2 to 38.5) |
| New or worsened joint pain: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| New or worsened joint pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=5 to <12 Years of age[5] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Fatigue, headache,chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 16 | 16 | 4 | 12 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 deg C | 12.5 (1.6 to 38.3) | 18.8 (4.0 to 45.6) | 100.0 (39.8 to 100.0) | 0 (0.0 to 26.5) |

| | | | | |
|---|---|---|---|---|
| Fever: 38.0 to 38.4 deg C | 0 (0.0 to 20.6) | 6.3 (0.2 to 30.2) | 75.0 (19.4 to 99.4) | 0 (0.0 to 26.5) |
| Fever: >38.4 to 38.9 deg C | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| Fever: >38.9 to 40.0 deg C | 6.3 (0.2 to 30.2) | 6.3 (0.2 to 30.2) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Fever: >40.0 deg C | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Fatigue: Any | 68.8 (41.3 to 89.0) | 62.5 (35.4 to 84.8) | 100.0 (39.8 to 100.0) | 75.0 (42.8 to 94.5) |
| Fatigue: Mild | 43.8 (19.8 to 70.1) | 25.0 (7.3 to 52.4) | 25.0 (0.6 to 80.6) | 58.3 (27.7 to 84.8) |
| Fatigue: Moderate | 25.0 (7.3 to 52.4) | 37.5 (15.2 to 64.6) | 75.0 (19.4 to 99.4) | 16.7 (2.1 to 48.4) |
| Fatigue: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Fatigue: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Headache: Any | 50.0 (24.7 to 75.3) | 56.3 (29.9 to 80.2) | 75.0 (19.4 to 99.4) | 33.3 (9.9 to 65.1) |
| Headache: Mild | 25.0 (7.3 to 52.4) | 25.0 (7.3 to 52.4) | 25.0 (0.6 to 80.6) | 25.0 (5.5 to 57.2) |
| Headache: Moderate | 25.0 (7.3 to 52.4) | 31.3 (11.0 to 58.7) | 50.0 (6.8 to 93.2) | 8.3 (0.2 to 38.5) |
| Headache: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Headache: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Chills: Any | 31.3 (11.0 to 58.7) | 43.8 (19.8 to 70.1) | 75.0 (19.4 to 99.4) | 33.3 (9.9 to 65.1) |
| Chills: Mild | 25.0 (7.3 to 52.4) | 25.0 (7.3 to 52.4) | 75.0 (19.4 to 99.4) | 33.3 (9.9 to 65.1) |
| Chills: Moderate | 6.3 (0.2 to 30.2) | 18.8 (4.0 to 45.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Chills: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Chills: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Vomiting: Any | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 8.3 (0.2 to 38.5) |
| Vomiting: Mild | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 8.3 (0.2 to 38.5) |
| Vomiting: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Vomiting: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Vomiting: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Diarrhea: Any | 6.3 (0.2 to 30.2) | 0 (0.0 to 20.6) | 50.0 (6.8 to 93.2) | 0 (0.0 to 26.5) |
| Diarrhea: Mild | 6.3 (0.2 to 30.2) | 0 (0.0 to 20.6) | 50.0 (6.8 to 93.2) | 0 (0.0 to 26.5) |
| Diarrhea: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Diarrhea: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| Diarrhea: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Any | 0 (0.0 to 20.6) | 18.8 (4.0 to 45.6) | 50.0 (6.8 to 93.2) | 8.3 (0.2 to 38.5) |
| New or worsened muscle pain: Mild | 0 (0.0 to 20.6) | 18.8 (4.0 to 45.6) | 0 (0.0 to 60.2) | 8.3 (0.2 to 38.5) |
| New or worsened muscle pain: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 50.0 (6.8 to 93.2) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened joint pain: Any | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| New or worsened joint pain: Mild | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |
| New or worsened joint pain: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 25.0 (0.6 to 80.6) | 0 (0.0 to 26.5) |
| New or worsened joint pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |

| | | | | |
|---|---|---|---|---|
| New or worsened joint pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 20.6) | 0 (0.0 to 60.2) | 0 (0.0 to 26.5) |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3:>=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3:>=5 to <12 Years of age[6] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: 5 to <12 Years BNT162b2 10 mcg | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 38 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever:>=38.0 deg C | 2.6 (0.1 to 13.8) | | | |
| Fever:38.0 to 38.4 deg C | 0 (0.0 to 9.3) | | | |
| Fever: >38.4 to 38.9 deg C | 0 (0.0 to 9.3) | | | |
| Fever: >38.9 to 40.0 deg C | 2.6 (0.1 to 13.8) | | | |
| Fever: >40.0 deg C | 0 (0.0 to 9.3) | | | |
| Fatigue: Any | 39.5 (24.0 to 56.6) | | | |
| Fatigue: Mild | 21.1 (9.6 to 37.3) | | | |
| Fatigue: Moderate | 15.8 (6.0 to 31.3) | | | |
| Fatigue: Severe | 2.6 (0.1 to 13.8) | | | |
| Fatigue: Grade 4 | 0 (0.0 to 9.3) | | | |

| | | | | |
|---|---|---|---|---|
| Headache: Any | 34.2 (19.6 to 51.4) | | | |
| Headache: Mild | 21.1 (9.6 to 37.3) | | | |
| Headache: Moderate | 10.5 (2.9 to 24.8) | | | |
| Headache: Severe | 2.6 (0.1 to 13.8) | | | |
| Headache: Grade 4 | 0 (0.0 to 9.3) | | | |
| Chills: Any | 15.8 (6.0 to 31.3) | | | |
| Chills: Mild | 13.2 (4.4 to 28.1) | | | |
| Chills: Moderate | 2.6 (0.1 to 13.8) | | | |
| Chills: Severe | 0 (0.0 to 9.3) | | | |
| Chills: Grade 4 | 0 (0.0 to 9.3) | | | |
| Vomiting: Any | 2.6 (0.1 to 13.8) | | | |
| Vomiting: Mild | 2.6 (0.1 to 13.8) | | | |
| Vomiting: Moderate | 0 (0.0 to 9.3) | | | |
| Vomiting: Severe | 0 (0.0 to 9.3) | | | |
| Vomiting: Grade 4 | 0 (0.0 to 9.3) | | | |
| Diarrhea: Any | 0 (0.0 to 9.3) | | | |
| Diarrhea: Mild | 0 (0.0 to 9.3) | | | |
| Diarrhea: Moderate | 0 (0.0 to 9.3) | | | |
| Diarrhea: Severe | 0 (0.0 to 9.3) | | | |
| Diarrhea: Grade 4 | 0 (0.0 to 9.3) | | | |
| New or worsened muscle pain: Any | 7.9 (1.7 to 21.4) | | | |
| New or worsened muscle pain: Mild | 2.6 (0.1 to 13.8) | | | |
| New or worsened muscle pain: Moderate | 5.3 (0.6 to 17.7) | | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 9.3) | | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 9.3) | | | |
| New or worsened joint pain: Any | 2.6 (0.1 to 13.8) | | | |
| New or worsened joint pain: Mild | 0 (0.0 to 9.3) | | | |
| New or worsened joint pain: Moderate | 2.6 (0.1 to 13.8) | | | |
| New or worsened joint pain: Severe | 0 (0.0 to 9.3) | | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 9.3) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age[7] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 32 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 0 (0.0 to 20.6) | 28.1 (13.7 to 46.7) | | |
| Redness: Mild | 0 (0.0 to 20.6) | 25.0 (11.5 to 43.4) | | |
| Redness: Moderate | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| Redness: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Redness: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Swelling: Any | 0 (0.0 to 20.6) | 9.4 (2.0 to 25.0) | | |
| Swelling: Mild | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| Swelling: Moderate | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| Swelling: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Swelling: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Pain at the injection site: Any | 31.3 (11.0 to 58.7) | 62.5 (43.7 to 78.9) | | |
| Pain at the injection site: Mild | 25.0 (7.3 to 52.4) | 56.3 (37.7 to 73.6) | | |
| Pain at the injection site: Moderate | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Pain at the injection site: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age[8] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 32 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 0 (0.0 to 20.6) | 15.6 (5.3 to 32.8) | | |
| Redness: Mild | 0 (0.0 to 20.6) | 15.6 (5.3 to 32.8) | | |
| Redness: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Redness: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Redness: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Swelling: Any | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| Swelling: Mild | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Swelling: Moderate | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| Swelling: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Swelling: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Pain at the injection site: Any | 37.5 (15.2 to 64.6) | 53.1 (34.7 to 70.9) | | |
| Pain at the injection site: Mild | 37.5 (15.2 to 64.6) | 43.8 (26.4 to 62.3) | | |
| Pain at the injection site: Moderate | 0 (0.0 to 20.6) | 9.4 (2.0 to 25.0) | | |
| Pain at the injection site: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age[9] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation. Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg) | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 26 | 13 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 3.8 (0.1 to 19.6) | 15.4 (1.9 to 45.4) | | |
| Redness: Mild | 3.8 (0.1 to 19.6) | 15.4 (1.9 to 45.4) | | |
| Redness: Moderate | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Redness: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Redness: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Swelling: Any | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Swelling: Mild | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Swelling: Moderate | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Swelling: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Swelling: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Pain at the injection site: Any | 34.6 (17.2 to 55.7) | 84.6 (54.6 to 98.1) | | |
| Pain at the injection site: Mild | 34.6 (17.2 to 55.7) | 38.5 (13.9 to 68.4) | | |
| Pain at the injection site: Moderate | 0 (0.0 to 13.2) | 38.5 (13.9 to 68.4) | | |
| Pain at the injection site: Severe | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age[10] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 32 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 deg C | 0 (0.0 to 20.6) | 18.8 (7.2 to 36.4) | | |
| Fever: 38.0 to 38.4 deg C | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| Fever: >38.4 to 38.9 deg C | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| Fever: >38.9 to 40.0 deg C | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| Fever: >40.0 deg C | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Fatigue: Any | 25.0 (7.3 to 52.4) | 46.9 (29.1 to 65.3) | | |
| Fatigue: Mild | 18.8 (4.0 to 45.6) | 34.4 (18.6 to 53.2) | | |
| Fatigue: Moderate | 6.3 (0.2 to 30.2) | 12.5 (3.5 to 29.0) | | |
| Fatigue: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Fatigue: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |

| | | | | |
|---|---|---|---|---|
| Headache: Any | 12.5 (1.6 to 38.3) | 9.4 (2.0 to 25.0) | | |
| Headache: Mild | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Headache: Moderate | 6.3 (0.2 to 30.2) | 3.1 (0.1 to 16.2) | | |
| Headache: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Headache: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Chills: Any | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Chills: Mild | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Chills: Moderate | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Chills: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Chills: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Vomiting: Any | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| Vomiting: Mild | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| Vomiting: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Vomiting: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Vomiting: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Diarrhea: Any | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Diarrhea: Mild | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Diarrhea: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Diarrhea: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Diarrhea: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened muscle pain: Any | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| New or worsened muscle pain: Mild | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| New or worsened muscle pain: Moderate | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Any | 6.3 (0.2 to 30.2) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Mild | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Moderate | 6.3 (0.2 to 30.2) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age

| | |
|---|---|
| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age[11] |

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 32 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 deg C | 6.3 (0.2 to 30.2) | 18.8 (7.2 to 36.4) | | |
| Fever: 38.0 to 38.4 deg C | 0 (0.0 to 20.6) | 9.4 (2.0 to 25.0) | | |
| Fever: >38.4 to 38.9 deg C | 6.3 (0.2 to 30.2) | 3.1 (0.1 to 16.2) | | |
| Fever: >38.9 to 40.0 deg C | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| Fever: >40.0 deg C | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Fatigue: Any | 25.0 (7.3 to 52.4) | 59.4 (40.6 to 76.3) | | |
| Fatigue: Mild | 12.5 (1.6 to 38.3) | 31.3 (16.1 to 50.0) | | |
| Fatigue: Moderate | 12.5 (1.6 to 38.3) | 28.1 (13.7 to 46.7) | | |
| Fatigue: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Fatigue: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Headache: Any | 12.5 (1.6 to 38.3) | 15.6 (5.3 to 32.8) | | |
| Headache: Mild | 6.3 (0.2 to 30.2) | 9.4 (2.0 to 25.0) | | |
| Headache: Moderate | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Headache: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Headache: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Chills: Any | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Chills: Mild | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| Chills: Moderate | 6.3 (0.2 to 30.2) | 0 (0.0 to 10.9) | | |
| Chills: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Chills: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |

| | | | | |
|---|---|---|---|---|
| Vomiting: Any | 6.3 (0.2 to 30.2) | 6.3 (0.8 to 20.8) | | |
| Vomiting: Mild | 6.3 (0.2 to 30.2) | 3.1 (0.1 to 16.2) | | |
| Vomiting: Moderate | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| Vomiting: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Vomiting: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Diarrhea: Any | 6.3 (0.2 to 30.2) | 12.5 (3.5 to 29.0) | | |
| Diarrhea: Mild | 6.3 (0.2 to 30.2) | 12.5 (3.5 to 29.0) | | |
| Diarrhea: Moderate | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Diarrhea: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| Diarrhea: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened muscle pain: Any | 0 (0.0 to 20.6) | 9.4 (2.0 to 25.0) | | |
| New or worsened muscle pain: Mild | 0 (0.0 to 20.6) | 6.3 (0.8 to 20.8) | | |
| New or worsened muscle pain: Moderate | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Any | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| New or worsened joint pain: Mild | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Moderate | 0 (0.0 to 20.6) | 3.1 (0.1 to 16.2) | | |
| New or worsened joint pain: Severe | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 20.6) | 0 (0.0 to 10.9) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age[12] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Fatigue, headache, chills, new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild: 1-2 times in 24 hours, moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea: mild: 2-3 loose stools in 24 hours, moderate: 4-5 loose stools in 24 hours, severe: 6 or more loose stools in 24 hours. Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg) | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 26 | 13 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 deg C | 0 (0.0 to 13.2) | 15.4 (1.9 to 45.4) | | |
| Fever: 38.0 to 38.4 deg C | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Fever: >38.4 to 38.9 deg C | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Fever: >38.9 to 40.0 deg C | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Fever: >40.0 deg C | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Fatigue: Any | 30.8 (14.3 to 51.8) | 53.8 (25.1 to 80.8) | | |
| Fatigue: Mild | 19.2 (6.6 to 39.4) | 23.1 (5.0 to 53.8) | | |
| Fatigue: Moderate | 11.5 (2.4 to 30.2) | 30.8 (9.1 to 61.4) | | |
| Fatigue: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Fatigue: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Headache: Any | 3.8 (0.1 to 19.6) | 23.1 (5.0 to 53.8) | | |
| Headache: Mild | 3.8 (0.1 to 19.6) | 15.4 (1.9 to 45.4) | | |
| Headache: Moderate | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Headache: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Headache: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Chills: Any | 0 (0.0 to 13.2) | 15.4 (1.9 to 45.4) | | |
| Chills: Mild | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Chills: Moderate | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| Chills: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Chills: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Vomiting: Any | 0 (0.0 to 13.2) | 23.1 (5.0 to 53.8) | | |
| Vomiting: Mild | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Vomiting: Moderate | 0 (0.0 to 13.2) | 23.1 (5.0 to 53.8) | | |
| Vomiting: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Vomiting: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Diarrhea: Any | 3.8 (0.1 to 19.6) | 7.7 (0.2 to 36.0) | | |
| Diarrhea: Mild | 3.8 (0.1 to 19.6) | 7.7 (0.2 to 36.0) | | |
| Diarrhea: Moderate | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| Diarrhea: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |

| | | | | |
|---|---|---|---|---|
| Diarrhea: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| New or worsened muscle pain: Any | 0 (0.0 to 13.2) | 15.4 (1.9 to 45.4) | | |
| New or worsened muscle pain: Mild | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| New or worsened muscle pain: Moderate | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| New or worsened joint pain: Any | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| New or worsened joint pain: Mild | 0 (0.0 to 13.2) | 7.7 (0.2 to 36.0) | | |
| New or worsened joint pain: Moderate | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| New or worsened joint pain: Severe | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 13.2) | 0 (0.0 to 24.7) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age[13] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)&Grade (G) 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]).Tenderness at injection site was graded as mild(hurts if gently touched),moderate(hurts if gently touched with crying),severe(causes limitation of limb movement)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person.Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 16 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 18.8 (4.0 to 45.6) | | | |
| Redness: Mild | 18.8 (4.0 to 45.6) | | | |

| | | | | |
|---|---|---|---|---|
| Redness: Moderate | 0 (0.0 to 20.6) | | | |
| Redness: Severe | 0 (0.0 to 20.6) | | | |
| Redness: Grade 4 | 0 (0.0 to 20.6) | | | |
| Swelling: Any | 6.3 (0.2 to 30.2) | | | |
| Swelling: Mild | 6.3 (0.2 to 30.2) | | | |
| Swelling: Moderate | 0 (0.0 to 20.6) | | | |
| Swelling: Severe | 0 (0.0 to 20.6) | | | |
| Swelling: Grade 4 | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Any | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Mild | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Moderate | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Severe | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Grade 4 | 0 (0.0 to 20.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age[14] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)&Grade (G) 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]).Tenderness at injection site was graded as mild(hurts if gently touched),moderate(hurts if gently touched with crying),severe(causes limitation of limb movement)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person.Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 16 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 0 (0.0 to 20.6) | | | |
| Redness: Mild | 0 (0.0 to 20.6) | | | |

| | | | | |
|---|---|---|---|---|
| Redness: Moderate | 0 (0.0 to 20.6) | | | |
| Redness: Severe | 0 (0.0 to 20.6) | | | |
| Redness: Grade 4 | 0 (0.0 to 20.6) | | | |
| Swelling: Any | 0 (0.0 to 20.6) | | | |
| Swelling: Mild | 0 (0.0 to 20.6) | | | |
| Swelling: Moderate | 0 (0.0 to 20.6) | | | |
| Swelling: Severe | 0 (0.0 to 20.6) | | | |
| Swelling: Grade 4 | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Any | 6.3 (0.2 to 30.2) | | | |
| Tenderness at the injection site: Mild | 6.3 (0.2 to 30.2) | | | |
| Tenderness at the injection site: Moderate | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Severe | 0 (0.0 to 20.6) | | | |
| Tenderness at the injection site: Grade 4 | 0 (0.0 to 20.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age[15] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)&G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]).Tenderness at injection site was graded as mild(hurts if gently touched),moderate(hurts if gently touched with crying),severe(causes limitation of limb movement)&G4 ER visit or hospitalisation for severe tenderness at injection site).G4 were classified by investigator or medically qualified person.Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N'= participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 15 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |

| | | | | |
|---|---|---|---|---|
| Redness: Any | 13.3 (1.7 to 40.5) | | | |
| Redness: Mild | 13.3 (1.7 to 40.5) | | | |
| Redness: Moderate | 0 (0.0 to 21.8) | | | |
| Redness: Severe | 0 (0.0 to 21.8) | | | |
| Redness: Grade 4 | 0 (0.0 to 21.8) | | | |
| Swelling: Any | 6.7 (0.2 to 31.9) | | | |
| Swelling: Mild | 6.7 (0.2 to 31.9) | | | |
| Swelling: Moderate | 0 (0.0 to 21.8) | | | |
| Swelling: Severe | 0 (0.0 to 21.8) | | | |
| Swelling: Grade 4 | 0 (0.0 to 21.8) | | | |
| Tenderness at the injection site: Any | 26.7 (7.8 to 55.1) | | | |
| Tenderness at the injection site: Mild | 26.7 (7.8 to 55.1) | | | |
| Tenderness at the injection site: Moderate | 0 (0.0 to 21.8) | | | |
| Tenderness at the injection site: Severe | 0 (0.0 to 21.8) | | | |
| Tenderness at the injection site: Grade 4 | 0 (0.0 to 21.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age[16] |
|---|---|

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Decreased appetite: mild (decreased interest in eating), moderate (decreased oral intake),severe (refusal to feed).Drowsiness: mild (increased or prolonged sleeping bouts), moderate (slightly subdued interfering with daily activity), severe (disabling; not interested in usual daily activity).Irritability: mild (easily consolable), moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 16 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 6.3 (0.2 to 30.2) | | | |
| Fever: 38.0 to 38.4 deg C | 6.3 (0.2 to 30.2) | | | |
| Fever: >38.4 to 38.9 deg C | 0 (0.0 to 20.6) | | | |
| Fever: >38.9 to 40.0 deg C | 0 (0.0 to 20.6) | | | |
| Fever: >40.0 deg C | 0 (0.0 to 20.6) | | | |
| Decreased appetite: Any | 6.3 (0.2 to 30.2) | | | |
| Decreased appetite: Mild | 0 (0.0 to 20.6) | | | |
| Decreased appetite: Moderate | 6.3 (0.2 to 30.2) | | | |
| Decreased appetite: Severe | 0 (0.0 to 20.6) | | | |
| Decreased appetite: Grade 4 | 0 (0.0 to 20.6) | | | |
| Drowsiness: Any | 25.0 (7.3 to 52.4) | | | |
| Drowsiness: Mild | 18.8 (4.0 to 45.6) | | | |
| Drowsiness: Moderate | 6.3 (0.2 to 30.2) | | | |
| Drowsiness: Severe | 0 (0.0 to 20.6) | | | |
| Drowsiness: Grade 4 | 0 (0.0 to 20.6) | | | |
| Irritability: Any | 43.8 (19.8 to 70.1) | | | |
| Irritability: Mild | 18.8 (4.0 to 45.6) | | | |
| Irritability: Moderate | 25.0 (7.3 to 52.4) | | | |
| Irritability: Severe | 0 (0.0 to 20.6) | | | |
| Irritability: Grade 4 | 0 (0.0 to 20.6) | | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age[17] |
|---|---|

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C.Decreased appetite: mild (decreased interest in eating), moderate (decreased oral intake),severe (refusal to feed).Drowsiness: mild (increased or prolonged sleeping bouts), moderate (slightly subdued interfering with daily activity), severe (disabling; not interested in usual daily activity).Irritability: mild (easily consolable), moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit/hospitalisation

and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 16 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 12.5 (1.6 to 38.3) | | | |
| Fever: 8.0 to 38.4 deg C | 12.5 (1.6 to 38.3) | | | |
| Fever: >38.4 to 38.9 deg C | 0 (0.0 to 20.6) | | | |
| Fever: >38.9 to 40.0 deg C | 0 (0.0 to 20.6) | | | |
| Fever: >40.0 deg C | 0 (0.0 to 20.6) | | | |
| Decreased appetite: Any | 12.5 (1.6 to 38.3) | | | |
| Decreased appetite: Mild | 12.5 (1.6 to 38.3) | | | |
| Decreased appetite: Moderate | 0 (0.0 to 20.6) | | | |
| Decreased appetite: Severe | 0 (0.0 to 20.6) | | | |
| Decreased appetite: Grade 4 | 0 (0.0 to 20.6) | | | |
| Drowsiness: Any | 6.3 (0.2 to 30.2) | | | |
| Drowsiness: Mild | 6.3 (0.2 to 30.2) | | | |
| Drowsiness: Moderate | 0 (0.0 to 20.6) | | | |
| Drowsiness: Severe | 0 (0.0 to 20.6) | | | |
| Drowsiness: Grade 4 | 0 (0.0 to 20.6) | | | |
| Irritability: Any | 31.3 (11.0 to 58.7) | | | |
| Irritability: Mild | 31.3 (11.0 to 58.7) | | | |
| Irritability: Moderate | 0 (0.0 to 20.6) | | | |
| Irritability: Severe | 0 (0.0 to 20.6) | | | |
| Irritability: Grade 4 | 0 (0.0 to 20.6) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants With Systemic Events Within 7 Days

## After Dose 3: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=6 Months to <2 Years of age[18] |
|---|---|

End point description:

Systemic events recorded in an e-diary and at unscheduled clinical assessments from Day 1 to 7 after Dose 3. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Decreased appetite: mild (decreased interest in eating), moderate (decreased oral intake),severe (refusal to feed).Drowsiness: mild (increased or prolonged sleeping bouts), moderate (slightly subdued interfering with daily activity), severe (disabling; not interested in usual daily activity).Irritability: mild (easily consolable), moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person. Events reported as AEs in the CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population was used.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 15 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 6.7 (0.2 to 31.9) | | | |
| Fever: 38.0 to 38.4 deg C | 0 (0.0 to 21.8) | | | |
| Fever: >38.4 to 38.9 deg C | 0 (0.0 to 21.8) | | | |
| Fever: >38.9 to 40.0 deg C | 6.7 (0.2 to 31.9) | | | |
| Fever: >40.0 deg C | 0 (0.0 to 21.8) | | | |
| Decreased appetite: Any | 13.3 (1.7 to 40.5) | | | |
| Decreased appetite: Mild | 6.7 (0.2 to 31.9) | | | |
| Decreased appetite: Moderate | 6.7 (0.2 to 31.9) | | | |
| Decreased appetite: Severe | 0 (0.0 to 21.8) | | | |
| Decreased appetite: Grade 4 | 0 (0.0 to 21.8) | | | |
| Drowsiness: Any | 6.7 (0.2 to 31.9) | | | |
| Drowsiness: Mild | 0 (0.0 to 21.8) | | | |
| Drowsiness: Moderate | 6.7 (0.2 to 31.9) | | | |
| Drowsiness: Severe | 0 (0.0 to 21.8) | | | |
| Drowsiness: Grade 4 | 0 (0.0 to 21.8) | | | |
| Irritability: Any | 26.7 (7.8 to 55.1) | | | |
| Irritability: Mild | 13.3 (1.7 to 40.5) | | | |
| Irritability: Moderate | 13.3 (1.7 to 40.5) | | | |

| | | | | |
|---|---|---|---|---|
| Irritability: Severe | 0 (0.0 to 21.8) | | | |
| Irritability: Grade 4 | 0 (0.0 to 21.8) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age[19] |
|---|---|

End point description:

An adverse event (AE) was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 16 | 16 | 4 | 12 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 43.8 (19.8 to 70.1) | 31.3 (11.0 to 58.7) | 50.0 (6.8 to 93.2) | 25.0 (5.5 to 57.2) |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age[20] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study

intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: 5 to <12 Years BNT162b2 10 mcg | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 38 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 15.8 (6.0 to 31.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=5 to <12 Years of age[21] |
|---|---|

End point description:

A serious adverse event (SAE) was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic.Exact 2-sided 95% CI based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | Phase 1:BNT162b2 (30/30 mcg): 5 to < 12 years of age | Phase 1:BNT162b2 (30/10 mcg): 5 to < 12 years of age |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 16 | 16 | 4 | 12 |
| Units: Percentage of participants | | | | |

| | | | | |
|---|---|---|---|---|
| number (confidence interval 95%) | 0 (0 to 0) | 0 (0 to 0) | 0 (0 to 0) | 0 (0 to 0) |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age[22] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 6 Months after Dose 3 (Approximately 6 months)

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: 5 to <12 Years BNT162b2 10 mcg | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 38 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=2 to <5 Years of age[23] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention.Exact 2-sided 95% CI based on the Clopper and Pearson method. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were

reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg) | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 27 | 13 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 11.1 (2.4 to 29.2) | 0 (0.0 to 24.7) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age[24] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 32 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 25.0 (7.3 to 52.4) | 37.5 (21.1 to 56.3) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=6 Months to <2 Years of age[25] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method.Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From dose 3 to 1 month after dose 3

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 15 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 6.7 (0.2 to 31.9) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=6 Months to <2 Years of age[26] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study

intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided 95% CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From dose 1 to 1 month after dose 2

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 16 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 12.5 (1.6 to 38.3) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=2 to <5 Years of age[27] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From dose 3 to 6 months after dose 3 (Approximately 6 months)

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 3 mcg) | Phase 1: BNT162b2: 2 to <5 Years of Age (Dose 3- 10 mcg) | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 27 | 13 | | |
| Units: Percentage of participants | | | | |

| | | | | |
|---|---|---|---|---|
| number (confidence interval 95%) | 0 (0 to 0) | 0 (0 to 0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age[28] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 16 | 32 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 0) | 0 (0 to 0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=6 Months to <2 Years of age[29] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic.Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population

included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From dose 3 to 6 months after dose 3 (Approximately 6 months)

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 15 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=6 Months to <2 Years of age

| End point title | Phase 1: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=6 Months to <2 Years of age[30] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic.Exact 2-sided 95% CI based on the Clopper and Pearson method.Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 16 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0 (0 to 0) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age[31] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo:5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 515 | 260 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 15.5 (12.5 to 19.0) | 6.2 (3.6 to 9.8) | | |
| Redness: Mild | 11.8 (9.2 to 15.0) | 5.4 (3.0 to 8.9) | | |
| Redness: Moderate | 3.7 (2.2 to 5.7) | 0.4 (0.0 to 2.1) | | |
| Redness: Severe | 0 (0.0 to 0.7) | 0.4 (0.0 to 2.1) | | |
| Redness: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Swelling: Any | 10.9 (8.3 to 13.9) | 4.6 (2.4 to 7.9) | | |
| Swelling: Mild | 7.6 (5.4 to 10.2) | 2.7 (1.1 to 5.5) | | |
| Swelling: Moderate | 3.3 (1.9 to 5.2) | 1.9 (0.6 to 4.4) | | |
| Swelling: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |

| | | | | |
|---|---|---|---|---|
| Swelling: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Pain at the injection site: Any | 72.4 (68.3 to 76.2) | 28.1 (22.7 to 34.0) | | |
| Pain at the injection site: Mild | 57.7 (53.3 to 62.0) | 23.5 (18.4 to 29.1) | | |
| Pain at the injection site: Moderate | 14.8 (11.8 to 18.1) | 4.6 (2.4 to 7.9) | | |
| Pain at the injection site: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age[32] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 475 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 2.1 (1.0 to 3.8) | | | |
| Redness: Mild | 1.5 (0.6 to 3.0) | | | |
| Redness: Moderate | 0.6 (0.1 to 1.8) | | | |
| Redness: Severe | 0 (0.0 to 0.8) | | | |
| Redness: Grade 4 | 0 (0.0 to 0.8) | | | |
| Swelling: Any | 4.4 (2.8 to 6.7) | | | |
| Swelling: Mild | 2.7 (1.5 to 4.6) | | | |

| | | | | |
|---|---|---|---|---|
| Swelling: Moderate | 1.7 (0.7 to 3.3) | | | |
| Swelling: Severe | 0 (0.0 to 0.8) | | | |
| Swelling: Grade 4 | 0 (0.0 to 0.8) | | | |
| Pain at the injection site: Any | 72.4 (68.2 to 76.4) | | | |
| Pain at the injection site: Mild | 43.8 (39.3 to 48.4) | | | |
| Pain at the injection site: Moderate | 28.2 (24.2 to 32.5) | | | |
| Pain at the injection site: Severe | 0.4 (0.1 to 1.5) | | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 0.8) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=5 to <12 Years of age[33] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N'= participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo: 5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 497 | 107 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 16.7 (13.5 to 20.3) | 1.9 (0.2 to 6.6) | | |
| Redness: Mild | 9.9 (7.4 to 12.8) | 1.9 (0.2 to 6.6) | | |
| Redness: Moderate | 6.8 (4.8 to 9.4) | 0 (0.0 to 3.4) | | |
| Redness: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |

| | | | | |
|---|---|---|---|---|
| Redness: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Swelling: Any | 11.5 (8.8 to 14.6) | 4.7 (1.5 to 10.6) | | |
| Swelling: Mild | 6.8 (4.8 to 9.4) | 2.8 (0.6 to 8.0) | | |
| Swelling: Moderate | 4.6 (3.0 to 6.9) | 1.9 (0.2 to 6.6) | | |
| Swelling: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Swelling: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Pain at the injection site: Any | 66.8 (62.5 to 70.9) | 23.4 (15.7 to 32.5) | | |
| Pain at the injection site: Mild | 48.3 (43.8 to 52.8) | 19.6 (12.6 to 28.4) | | |
| Pain at the injection site: Moderate | 18.5 (15.2 to 22.2) | 3.7 (1.0 to 9.3) | | |
| Pain at the injection site: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: Troponin Group: >=12 to <16 Years of age[34] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 448 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 0.9 (0.2 to 2.3) | | | |

| | | | | |
|---|---|---|---|---|
| Redness: Mild | 0.4 (0.1 to 1.6) | | | |
| Redness: Moderate | 0.2 (0.0 to 1.2) | | | |
| Redness: Severe | 0.2 (0.0 to 1.2) | | | |
| Redness: Grade 4 | 0 (0.0 to 0.8) | | | |
| Swelling: Any | 1.8 (0.8 to 3.5) | | | |
| Swelling: Mild | 0.9 (0.2 to 2.3) | | | |
| Swelling: Moderate | 0.9 (0.2 to 2.3) | | | |
| Swelling: Severe | 0 (0.0 to 0.8) | | | |
| Swelling: Grade 4 | 0 (0.0 to 0.8) | | | |
| Pain at the injection site: Any | 57.8 (53.1 to 62.4) | | | |
| Pain at the injection site: Mild | 36.6 (32.1 to 41.3) | | | |
| Pain at the injection site: Moderate | 20.8 (17.1 to 24.8) | | | |
| Pain at the injection site: Severe | 0.4 (0.1 to 1.6) | | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 0.8) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age

| | |
|---|---|
| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age[35] |

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm),moderate (>2.0 to 7.0 cm), severe (>7.0 cm) and Grade 4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and Grade 4 ER visit or hospitalisation for severe pain at injection site). Grade 4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N'= participants evaluable for this endpoint.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo:5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 394 | 0[36] | | |
| Units: Percentage of participants | | | | |

| number (confidence interval 95%) | | | | |
|---|---|---|---|---|
| Redness: Any | 17.0 (13.4 to 21.1) | ( to ) | | |
| Redness: Mild | 11.2 (8.2 to 14.7) | ( to ) | | |
| Redness: Moderate | 5.8 (3.7 to 8.6) | ( to ) | | |
| Redness: Severe | 0 (0.0 to 0.9) | ( to ) | | |
| Redness: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| Swelling: Any | 12.7 (9.6 to 16.4) | ( to ) | | |
| Swelling: Mild | 9.4 (6.7 to 12.7) | ( to ) | | |
| Swelling: Moderate | 3.3 (1.8 to 5.6) | ( to ) | | |
| Swelling: Severe | 0 (0.0 to 0.9) | ( to ) | | |
| Swelling: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| Pain at the injection site: Any | 69.3 (64.5 to 73.8) | ( to ) | | |
| Pain at the injection site: Mild | 48.0 (42.9 to 53.0) | ( to ) | | |
| Pain at the injection site: Moderate | 20.8 (16.9 to 25.2) | ( to ) | | |
| Pain at the injection site: Severe | 0.5 (0.1 to 1.8) | ( to ) | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |

Notes:

[36] - No participants received dose 3 from this cohort.

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age[37] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild >2.0 to 5.0 cm),moderate (>5.0 to 10.0), severe >10.0 cm) and G4(necrosis [redness and swelling] or exfoliative dermatitis [redness]). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and G4 ER visit or hospitalisation for severe pain at injection site). G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population =all participants who received at least 1 dose of study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[37] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 405 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 3.5 (1.9 to 5.7) | | | |
| Redness: Mild | 3.0 (1.5 to 5.1) | | | |
| Redness: Moderate | 0.5 (0.1 to 1.8) | | | |
| Redness: Severe | 0 (0.0 to 0.9) | | | |
| Redness: Grade 4 | 0 (0.0 to 0.9) | | | |
| Swelling: Any | 3.0 (1.5 to 5.1) | | | |
| Swelling: Mild | 2.0 (0.9 to 3.9) | | | |
| Swelling: Moderate | 1.0 (0.3 to 2.5) | | | |
| Swelling: Severe | 0 (0.0 to 0.9) | | | |
| Swelling: Grade 4 | 0 (0.0 to 0.9) | | | |
| Pain at the injection site: Any | 63.5 (58.6 to 68.2) | | | |
| Pain at the injection site: Mild | 35.8 (31.1 to 40.7) | | | |
| Pain at the injection site: Moderate | 27.4 (23.1 to 32.0) | | | |
| Pain at the injection site: Severe | 0.2 (0.0 to 1.4) | | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 0.9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1:Troponin Group: >=5 to <12 Years of age[38] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[38] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo:5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 515 | 260 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >= 38.0 | 1.4 (0.5 to 2.8) | 3.1 (1.3 to 6.0) | | |
| Fever: 38.0 to 38.4 deg C | 0.8 (0.2 to 2.0) | 1.9 (0.6 to 4.4) | | |
| Fever: >38.4 to 38.9 deg C | 0.6 (0.1 to 1.7) | 1.2 (0.2 to 3.3) | | |
| Fever: >38.9 to 40.0 deg C | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Fever: >40.0 deg C | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Fatigue: Any | 37.1 (32.9 to 41.4) | 37.7 (31.8 to 43.9) | | |
| Fatigue: Mild | 24.1 (20.4 to 28.0) | 23.8 (18.8 to 29.5) | | |
| Fatigue: Moderate | 13.0 (10.2 to 16.2) | 13.1 (9.2 to 17.8) | | |
| Fatigue: Severe | 0 (0.0 to 0.7) | 0.8 (0.1 to 2.8) | | |
| Fatigue: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Headache: Any | 25.4 (21.7 to 29.4) | 25.8 (20.6 to 31.5) | | |
| Headache: Mild | 18.3 (15.0 to 21.9) | 19.2 (14.6 to 24.6) | | |
| Headache: Moderate | 6.8 (4.8 to 9.3) | 6.5 (3.9 to 10.3) | | |
| Headache: Severe | 0.4 (0.0 to 1.4) | 0 (0.0 to 1.4) | | |
| Headache: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Chills: Any | 7.2 (5.1 to 9.8) | 9.6 (6.3 to 13.9) | | |
| Chills: Mild | 5.6 (3.8 to 8.0) | 6.5 (3.9 to 10.3) | | |
| Chills: Moderate | 1.4 (0.5 to 2.8) | 3.1 (1.3 to 6.0) | | |
| Chills: Severe | 0.2 (0.0 to 1.1) | 0 (0.0 to 1.4) | | |
| Chills: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Vomiting: Any | 1.7 (0.8 to 3.3) | 2.3 (0.9 to 5.0) | | |
| Vomiting: Mild | 1.6 (0.7 to 3.0) | 1.9 (0.6 to 4.4) | | |
| Vomiting: Moderate | 0.2 (0.0 to 1.1) | 0.4 (0.0 to 2.1) | | |
| Vomiting: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Vomiting: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Diarrhea: Any | 6.2 (4.3 to 8.7) | 8.5 (5.4 to 12.5) | | |
| Diarrhea: Mild | 6.0 (4.1 to 8.4) | 8.1 (5.1 to 12.1) | | |
| Diarrhea: Moderate | 0.2 (0.0 to 1.1) | 0.4 (0.0 to 2.1) | | |
| Diarrhea: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| Diarrhea: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| New or worsened muscle pain: Any | 11.7 (9.0 to 14.7) | 10.0 (6.6 to 14.3) | | |

| | | | | |
|---|---|---|---|---|
| New or worsened muscle pain: Mild | 8.2 (5.9 to 10.9) | 7.7 (4.8 to 11.6) | | |
| New or worsened muscle pain: Moderate | 3.5 (2.1 to 5.5) | 2.3 (0.9 to 5.0) | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| New or worsened joint pain: Any | 5.2 (3.5 to 7.5) | 6.9 (4.2 to 10.7) | | |
| New or worsened joint pain: Mild | 4.5 (2.9 to 6.6) | 5.4 (3.0 to 8.9) | | |
| New or worsened joint pain: Moderate | 0.8 (0.2 to 2.0) | 1.5 (0.4 to 3.9) | | |
| New or worsened joint pain: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 1.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age

| | |
|---|---|
| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: Troponin Group: >=12 to <16 Years of age[39] |

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 1.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[39] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 475 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever:>=38.0 | 4.2 (2.6 to 6.4) | | | |
| Fever: 8.0 to 38.4 deg C | 2.3 (1.2 to 4.1) | | | |
| Fever: >38.4 to 38.9 deg C | 1.3 (0.5 to 2.7) | | | |
| Fever: >38.9 to 40.0 deg C | 0.6 (0.1 to 1.8) | | | |

| | | | | |
|---|---|---|---|---|
| Fever: >40.0 deg C | 0 (0.0 to 0.8) | | | |
| Fatigue: Any | 42.3 (37.8 to 46.9) | | | |
| Fatigue: Mild | 26.3 (22.4 to 30.5) | | | |
| Fatigue: Moderate | 15.6 (12.4 to 19.2) | | | |
| Fatigue: Severe | 0.4 (0.1 to 1.5) | | | |
| Fatigue: Grade 4 | 0 (0.0 to 0.8) | | | |
| Headache: Any | 33.3 (29.0 to 37.7) | | | |
| Headache: Mild | 22.9 (19.2 to 27.0) | | | |
| Headache: Moderate | 10.3 (7.7 to 13.4) | | | |
| Headache: Severe | 0 (0.0 to 0.8) | | | |
| Headache: Grade 4 | 0 (0.0 to 0.8) | | | |
| Chills: Any | 11.4 (8.7 to 14.6) | | | |
| Chills: Mild | 8.6 (6.3 to 11.5) | | | |
| Chills: Moderate | 2.5 (1.3 to 4.4) | | | |
| Chills: Severe | 0.2 (0.0 to 1.2) | | | |
| Chills: Grade 4 | 0 (0.0 to 0.8) | | | |
| Vomiting: Any | 2.9 (1.6 to 4.9) | | | |
| Vomiting: Mild | 2.7 (1.5 to 4.6) | | | |
| Vomiting: Moderate | 0.2 (0.0 to 1.2) | | | |
| Vomiting: Severe | 0 (0.0 to 0.8) | | | |
| Vomiting: Grade 4 | 0 (0.0 to 0.8) | | | |
| Diarrhea: Any | 9.1 (6.6 to 12.0) | | | |
| Diarrhea: Mild | 6.9 (4.8 to 9.6) | | | |
| Diarrhea: Moderate | 2.1 (1.0 to 3.8) | | | |
| Diarrhea: Severe | 0 (0.0 to 0.8) | | | |
| Diarrhea: Grade 4 | 0 (0.0 to 0.8) | | | |
| New or worsened muscle pain: Any | 26.3 (22.4 to 30.5) | | | |
| New or worsened muscle pain: Mild | 14.7 (11.7 to 18.2) | | | |
| New or worsened muscle pain: Moderate | 10.9 (8.3 to 14.1) | | | |
| New or worsened muscle pain: Severe | 0.6 (0.1 to 1.8) | | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 0.8) | | | |
| New or worsened joint pain: Any | 10.5 (7.9 to 13.6) | | | |
| New or worsened joint pain: Mild | 5.1 (3.3 to 7.4) | | | |
| New or worsened joint pain: Moderate | 5.5 (3.6 to 7.9) | | | |
| New or worsened joint pain: Severe | 0 (0.0 to 0.8) | | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 0.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2:Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2:Troponin Group: >=5 to <12 Years of age[40] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[40] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo:5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 497 | 107 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 5.0 (3.3 to 7.3) | 0 (0.0 to 3.4) | | |
| Fever:38.0 to 38.4 deg C | 2.2 (1.1 to 3.9) | 0 (0.0 to 3.4) | | |
| Fever: >38.4 to 38.9 deg C | 1.8 (0.8 to 3.4) | 0 (0.0 to 3.4) | | |
| Fever: >38.9 to 40.0 deg C | 1.0 (0.3 to 2.3) | 0 (0.0 to 3.4) | | |
| Fever: >40.0 deg C | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Fatigue: Any | 38.2 (33.9 to 42.7) | 29.0 (20.6 to 38.5) | | |
| Fatigue: Mild | 22.5 (18.9 to 26.5) | 15.9 (9.5 to 24.2) | | |
| Fatigue: Moderate | 15.5 (12.4 to 19.0) | 13.1 (7.3 to 21.0) | | |
| Fatigue: Severe | 0.2 (0.0 to 1.1) | 0 (0.0 to 3.4) | | |
| Fatigue: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Headache: Any | 30.2 (26.2 to 34.4) | 20.6 (13.4 to 29.5) | | |
| Headache: Mild | 20.1 (16.7 to 23.9) | 14.0 (8.1 to 22.1) | | |
| Headache: Moderate | 9.9 (7.4 to 12.8) | 6.5 (2.7 to 13.0) | | |
| Headache: Severe | 0.2 (0.0 to 1.1) | 0 (0.0 to 3.4) | | |
| Headache: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Chills: Any | 9.1 (6.7 to 11.9) | 7.5 (3.3 to 14.2) | | |
| Chills: Mild | 5.8 (3.9 to 8.3) | 6.5 (2.7 to 13.0) | | |

| | | | | |
|---|---|---|---|---|
| Chills: Moderate | 3.2 (1.9 to 5.2) | 0.9 (0.0 to 5.1) | | |
| Chills: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Chills: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Vomiting: Any | 2.0 (1.0 to 3.7) | 3.7 (1.0 to 9.3) | | |
| Vomiting: Mild | 1.8 (0.8 to 3.4) | 2.8 (0.6 to 8.0) | | |
| Vomiting: Moderate | 0.2 (0.0 to 1.1) | 0.9 (0.0 to 5.1) | | |
| Vomiting: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Vomiting: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| Diarrhea: Any | 7.4 (5.3 to 10.1) | 5.6 (2.1 to 11.8) | | |
| Diarrhea: Mild | 7.0 (5.0 to 9.7) | 5.6 (2.1 to 11.8) | | |
| Diarrhea: Moderate | 0.2 (0.0 to 1.1) | 0 (0.0 to 3.4) | | |
| Diarrhea: Severe | 0.2 (0.0 to 1.1) | 0 (0.0 to 3.4) | | |
| Diarrhea: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| New or worsened muscle pain: Any | 14.7 (11.7 to 18.1) | 11.2 (5.9 to 18.8) | | |
| New or worsened muscle pain: Mild | 9.3 (6.9 to 12.2) | 9.3 (4.6 to 16.5) | | |
| New or worsened muscle pain: Moderate | 5.4 (3.6 to 7.8) | 1.9 (0.2 to 6.6) | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| New or worsened joint pain: Any | 6.4 (4.4 to 9.0) | 6.5 (2.7 to 13.0) | | |
| New or worsened joint pain: Mild | 4.2 (2.6 to 6.4) | 6.5 (2.7 to 13.0) | | |
| New or worsened joint pain: Moderate | 2.2 (1.1 to 3.9) | 0 (0.0 to 3.4) | | |
| New or worsened joint pain: Severe | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 0.7) | 0 (0.0 to 3.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: Troponin group: >=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: Troponin group: >=12 to <16 Years of age[41] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 2.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 448 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 3.3 (1.9 to 5.5) | | | |
| Fever:38.0 to 38.4 deg C | 1.6 (0.6 to 3.2) | | | |
| Fever: >38.4 to 38.9 deg C | 1.3 (0.5 to 2.9) | | | |
| Fever: >38.9 to 40.0 deg C | 0.4 (0.1 to 1.6) | | | |
| Fever: >40.0 deg C | 0 (0.0 to 0.8) | | | |
| Fatigue: Any | 36.4 (31.9 to 41.0) | | | |
| Fatigue: Mild | 21.0 (17.3 to 25.1) | | | |
| Fatigue: Moderate | 15.0 (11.8 to 18.6) | | | |
| Fatigue: Severe | 0.4 (0.1 to 1.6) | | | |
| Fatigue: Grade 4 | 0 (0.0 to 0.8) | | | |
| Headache: Any | 33.3 (28.9 to 37.8) | | | |
| Headache: Mild | 19.4 (15.9 to 23.4) | | | |
| Headache: Moderate | 13.2 (10.2 to 16.7) | | | |
| Headache: Severe | 0.7 (0.1 to 1.9) | | | |
| Headache: Grade 4 | 0 (0.0 to 0.8) | | | |
| Chills: Any | 11.2 (8.4 to 14.4) | | | |
| Chills: Mild | 7.4 (5.1 to 10.2) | | | |
| Chills: Moderate | 3.8 (2.2 to 6.0) | | | |
| Chills: Severe | 0 (0.0 to 0.8) | | | |
| Chills: Grade 4 | 0 (0.0 to 0.8) | | | |
| Vomiting: Any | 2.2 (1.1 to 4.1) | | | |
| Vomiting: Mild | 2.0 (0.9 to 3.8) | | | |
| Vomiting: Moderate | 0.2 (0.0 to 1.2) | | | |
| Vomiting: Severe | 0 (0.0 to 0.8) | | | |
| Vomiting: Grade 4 | 0 (0.0 to 0.8) | | | |
| Diarrhea: Any | 7.1 (4.9 to 9.9) | | | |
| Diarrhea: Mild | 5.1 (3.3 to 7.6) | | | |
| Diarrhea: Moderate | 1.8 (0.8 to 3.5) | | | |
| Diarrhea: Severe | 0.2 (0.0 to 1.2) | | | |
| Diarrhea: Grade 4 | 0 (0.0 to 0.8) | | | |
| New or worsened muscle pain: Any | 19.6 (16.1 to 23.6) | | | |
| New or worsened muscle pain: Mild | 12.5 (9.6 to 15.9) | | | |

| | | | | |
|---|---|---|---|---|
| New or worsened muscle pain: Moderate | 6.9 (4.7 to 9.7) | | | |
| New or worsened muscle pain: Severe | 0.2 (0.0 to 1.2) | | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 0.8) | | | |
| New or worsened joint pain: Any | 6.7 (4.6 to 9.4) | | | |
| New or worsened joint pain: Mild | 3.8 (2.2 to 6.0) | | | |
| New or worsened joint pain: Moderate | 2.7 (1.4 to 4.6) | | | |
| New or worsened joint pain: Severe | 0.2 (0.0 to 1.2) | | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 0.8) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=5 to <12 Years of age[42] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[42] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo:5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 394 | 0[43] | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 4.6 (2.7 to 7.1) | ( to ) | | |
| Fever:38.0 to 38.4 deg C | 2.5 (1.2 to 4.6) | ( to ) | | |
| Fever: >38.4 to 38.9 deg C | 1.0 (0.3 to 2.6) | ( to ) | | |
| Fever: >38.9 to 40.0 deg C | 1.0 (0.3 to 2.6) | ( to ) | | |
| Fever: >40.0 deg C | 0 (0.0 to 0.9) | ( to ) | | |
| Fatigue: Any | 38.8 (34.0 to 43.8) | ( to ) | | |

| | | | | |
|---|---|---|---|---|
| Fatigue: Mild | 26.4 (22.1 to 31.0) | ( to ) | | |
| Fatigue: Moderate | 11.9 (8.9 to 15.5) | ( to ) | | |
| Fatigue: Severe | 0.5 (0.1 to 1.8) | ( to ) | | |
| Fatigue: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| Headache: Any | 23.6 (19.5 to 28.1) | ( to ) | | |
| Headache: Mild | 16.2 (12.7 to 20.3) | ( to ) | | |
| Headache: Moderate | 6.9 (4.6 to 9.8) | ( to ) | | |
| Headache: Severe | 0.5 (0.1 to 1.8) | ( to ) | | |
| Headache: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| Chills: Any | 8.9 (6.3 to 12.1) | ( to ) | | |
| Chills: Mild | 5.8 (3.7 to 8.6) | ( to ) | | |
| Chills: Moderate | 2.8 (1.4 to 4.9) | ( to ) | | |
| Chills: Severe | 0.3 (0.0 to 1.4) | ( to ) | | |
| Chills: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| Vomiting: Any | 1.8 (0.7 to 3.6) | ( to ) | | |
| Vomiting: Mild | 1.5 (0.6 to 3.3) | ( to ) | | |
| Vomiting: Moderate | 0.3 (0.0 to 1.4) | ( to ) | | |
| Vomiting: Severe | 0 (0.0 to 0.9) | ( to ) | | |
| Vomiting: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| Diarrhea: Any | 4.8 (2.9 to 7.4) | ( to ) | | |
| Diarrhea: Mild | 4.6 (2.7 to 7.1) | ( to ) | | |
| Diarrhea: Moderate | 0.3 (0.0 to 1.4) | ( to ) | | |
| Diarrhea: Severe | 0 (0.0 to 0.9) | ( to ) | | |
| Diarrhea: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| New or worsened muscle pain: Any | 18.5 (14.8 to 22.7) | ( to ) | | |
| New or worsened muscle pain: Mild | 10.2 (7.4 to 13.6) | ( to ) | | |
| New or worsened muscle pain: Moderate | 8.4 (5.8 to 11.6) | ( to ) | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 0.9) | ( to ) | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |
| New or worsened joint pain: Any | 5.8 (3.7 to 8.6) | ( to ) | | |
| New or worsened joint pain: Mild | 4.1 (2.3 to 6.5) | ( to ) | | |
| New or worsened joint pain: Moderate | 1.8 (0.7 to 3.6) | ( to ) | | |
| New or worsened joint pain: Severe | 0 (0.0 to 0.9) | ( to ) | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 0.9) | ( to ) | | |

Notes:

[43] - No participants received dose 3 from this cohort.

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age

| | |
|---|---|
| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: Troponin Group: >=12 to <16 Years of age[44] |

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments from upto Day 7 after Dose 3.Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C, >38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain and new or worsened joint pain:mild (did not interfere with activity),moderate (some interference with activity),severe (prevented daily routine activity).Vomiting:mild:1-2 times in 24 hours,moderate: >2 times in 24 hours,severe: required intravenous hydration.Diarrhea:mild: 2-3 loose stools in 24 hours, moderate:4-5 loose stools in 24 hours,severe: 6 or more loose stools in 24 hours.Grade 4 for all events: ER visit/hospitalisation and were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95% CI based on Clopper and Pearson method.Safety population.'N'= participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[44] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 405 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 3.5 (1.9 to 5.7) | | | |
| Fever: 8.0 to 38.4 deg C | 1.7 (0.7 to 3.5) | | | |
| Fever: >38.4 to 38.9 deg C | 1.2 (0.4 to 2.9) | | | |
| Fever: >38.9 to 40.0 deg C | 0.5 (0.1 to 1.8) | | | |
| Fever: >40.0 deg C | 0 (0.0 to 0.9) | | | |
| Fatigue: Any | 36.8 (32.1 to 41.7) | | | |
| Fatigue: Mild | 21.7 (17.8 to 26.1) | | | |
| Fatigue: Moderate | 14.8 (11.5 to 18.7) | | | |
| Fatigue: Severe | 0.2 (0.0 to 1.4) | | | |
| Fatigue: Grade 4 | 0 (0.0 to 0.9) | | | |
| Headache: Any | 35.3 (30.7 to 40.2) | | | |
| Headache: Mild | 23.0 (19.0 to 27.4) | | | |
| Headache: Moderate | 11.6 (8.7 to 15.1) | | | |
| Headache: Severe | 0.7 (0.2 to 2.1) | | | |
| Headache: Grade 4 | 0 (0.0 to 0.9) | | | |
| Chills: Any | 12.8 (9.7 to 16.5) | | | |
| Chills: Mild | 8.4 (5.9 to 11.5) | | | |
| Chills: Moderate | 4.4 (2.7 to 6.9) | | | |
| Chills: Severe | 0 (0.0 to 0.9) | | | |
| Chills: Grade 4 | 0 (0.0 to 0.9) | | | |
| Vomiting: Any | 2.7 (1.4 to 4.8) | | | |
| Vomiting: Mild | 2.2 (1.0 to 4.2) | | | |

| | | | | |
|---|---|---|---|---|
| Vomiting: Moderate | 0.5 (0.1 to 1.8) | | | |
| Vomiting: Severe | 0 (0.0 to 0.9) | | | |
| Vomiting: Grade 4 | 0 (0.0 to 0.9) | | | |
| Diarrhea: Any | 4.4 (2.7 to 6.9) | | | |
| Diarrhea: Mild | 4.0 (2.3 to 6.3) | | | |
| Diarrhea: Moderate | 0.5 (0.1 to 1.8) | | | |
| Diarrhea: Severe | 0 (0.0 to 0.9) | | | |
| Diarrhea: Grade 4 | 0 (0.0 to 0.9) | | | |
| New or worsened muscle pain: Any | 18.8 (15.1 to 22.9) | | | |
| New or worsened muscle pain: Mild | 10.6 (7.8 to 14.0) | | | |
| New or worsened muscle pain: Moderate | 8.1 (5.7 to 11.3) | | | |
| New or worsened muscle pain: Severe | 0 (0.0 to 0.9) | | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 0.9) | | | |
| New or worsened joint pain: Any | 6.4 (4.2 to 9.3) | | | |
| New or worsened joint pain: Mild | 4.0 (2.3 to 6.3) | | | |
| New or worsened joint pain: Moderate | 2.5 (1.2 to 4.5) | | | |
| New or worsened joint pain: Severe | 0 (0.0 to 0.9) | | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 0.9) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=5 to <12 Years of age

| | |
|---|---|
| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=5 to <12 Years of age[45] |

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[45] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3:Troponin group:BNT162 b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo: 5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 518 | 260 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 7.1 (5.1 to 9.7) | 8.1 (5.1 to 12.1) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: Troponin Group: >=12 to <16 Years of age[46] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[46] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 487 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 5.3 (3.5 to 7.7) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group: >=5 to <12 Years of age[47] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[47] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo: 5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 418 | 202 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 11.5 (8.6 to 14.9) | 15.3 (10.7 to 21.1) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group:>=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: Troponin Group:>=12 to <16 Years of age[48] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[48] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 433 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 1.4 (0.5 to 3.0) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : Troponin Group: >=5 to <12 Years of age[49] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162 b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo: 5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 518 | 260 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.2 (0.0 to 1.1) | 0 (0.0 to 1.4) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: Troponin Group: >=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: Troponin Group: >=12 to <16 Years of age[50] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[50] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 487 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.4 (0.0 to 1.5) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=5 to <12 Years of age[51] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation for severe pain at injection site).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3096 | 1532 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (3096,1532) | 14.0 (12.8 to 15.3) | 5.9 (4.8 to 7.2) | | |
| Redness: Mild (3096,1532) | 9.3 (8.3 to 10.3) | 5.1 (4.0 to 6.3) | | |
| Redness: Moderate (3096,1532) | 4.7 (4.0 to 5.5) | 0.7 (0.4 to 1.3) | | |
| Redness: Severe (3096,1532) | 0.0 (0.0 to 0.2) | 0.1 (0.0 to 0.5) | | |
| Redness: Grade 4 (3096,1532) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Swelling: Any (3096,1532) | 10.3 (9.3 to 11.5) | 3.0 (2.2 to 4.0) | | |
| Swelling: Mild (3096,1532) | 5.7 (4.9 to 6.6) | 1.8 (1.2 to 2.6) | | |
| Swelling: Moderate (3096,1532) | 4.6 (3.9 to 5.4) | 1.2 (0.7 to 1.9) | | |
| Swelling: Severe (3096,1532) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.2) | | |
| Swelling: Grade 4 (3096,1532) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Pain at the injection site: Any (3096,1531) | 72.9 (71.3 to 74.5) | 31.5 (29.2 to 33.9) | | |
| Pain at the injection site: Mild (3096,1531) | 58.5 (56.7 to 60.2) | 28.3 (26.1 to 30.7) | | |
| Pain at the injection site: Moderate (3096,1531) | 14.3 (13.1 to 15.6) | 3.1 (2.3 to 4.1) | | |
| Pain at the injection site: Severe (3096,1531) | 0.2 (0.1 to 0.4) | 0 (0.0 to 0.2) | | |
| Pain at the injection site: Grade 4 (3096,1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : Troponin Group:>=12 to <16 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : Troponin Group:>=12 to <16 Years of age[52] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 6 months after Dose 3

Notes:

[52] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162 b2 (30 mcg):12 to <16 years | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 433 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 1.4 (0.5 to 3.0) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: Troponin Group: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: Troponin Group: >=5 to <12 Years of age[53] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[53] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3:Troponin group:BNT162 b2 (10 mcg):5 to <12 years | Phase 2/3:Troponin group:Placebo: 5 to <12 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 418 | 202 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.5 (0.1 to 1.7) | 0 (0.0 to 1.8) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=5 to <12 Years of age[54] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation for severe pain at injection site).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[54] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3064 | 1522 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (3064, 1522) | 18.8 (17.4 to 20.2) | 5.2 (4.1 to 6.4) | | |
| Redness: Mild (3064, 1522) | 10.3 (9.2 to 11.4) | 3.7 (2.8 to 4.8) | | |
| Redness: Moderate (3064, 1522) | 8.4 (7.4 to 9.4) | 1.3 (0.8 to 2.0) | | |
| Redness: Severe (3064, 1522) | 0.1 (0.0 to 0.3) | 0.1 (0.0 to 0.5) | | |
| Redness: Grade 4 (3064, 1522) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Swelling: Any (3064, 1522) | 14.7 (13.5 to 16.0) | 2.7 (1.9 to 3.6) | | |
| Swelling: Mild (3064, 1522) | 8.1 (7.1 to 9.1) | 2.0 (1.3 to 2.8) | | |
| Swelling: Moderate (3064, 1522) | 6.6 (5.8 to 7.6) | 0.7 (0.4 to 1.3) | | |
| Swelling: Severe (3064, 1522) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Swelling: Grade 4 (3064, 1522) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Pain at the injection site: Any (3064, 1521) | 71.2 (69.5 to 72.8) | 28.5 (26.3 to 30.9) | | |

| | | | | |
|---|---|---|---|---|
| Pain at the injection site: Mild (3064, 1521) | 53.6 (51.8 to 55.4) | 25.6 (23.4 to 27.8) | | |
| Pain at the injection site: Moderate (3064, 1521) | 17.4 (16.1 to 18.8) | 2.9 (2.1 to 3.9) | | |
| Pain at the injection site: Severe (3064, 1521) | 0.2 (0.1 to 0.4) | 0.1 (0.0 to 0.4) | | |
| Pain at the injection site: Grade 4 (3064, 1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.4) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=5 to <12 Years of age[55] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation for severe pain at injection site).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[55] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 2265 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any | 15.6 (14.2 to 17.2) | | | |
| Redness: Mild | 9.4 (8.3 to 10.7) | | | |
| Redness: Moderate | 6.1 (5.1 to 7.2) | | | |
| Redness: Severe | 0.1 (0.0 to 0.3) | | | |
| Redness: Grade 4 | 0 (0.0 to 0.2) | | | |
| Swelling: Any | 12.6 (11.3 to 14.1) | | | |
| Swelling: Mild | 6.5 (5.6 to 7.6) | | | |
| Swelling: Moderate | 6.1 (5.1 to 7.2) | | | |
| Swelling: Severe | 0 (0.0 to 0.2) | | | |

| | | | | |
|---|---|---|---|---|
| Swelling: Grade 4 | 0 (0.0 to 0.2) | | | |
| Pain at the injection site: Any | 69.2 (67.3 to 71.1) | | | |
| Pain at the injection site: Mild | 48.0 (46.0 to 50.1) | | | |
| Pain at the injection site: Moderate | 20.9 (19.3 to 22.7) | | | |
| Pain at the injection site: Severe | 0.3 (0.1 to 0.6) | | | |
| Pain at the injection site: Grade 4 | 0 (0.0 to 0.2) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=5 to <12 Years of age[56] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments upto Day 7 after Dose 1. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain &joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 h,moderate:>2 times in 24 h, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events: ER visit/hospitalisation & were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population was used. 'N= participants evaluable for this endpoint & 'n'= participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[56] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3096 | 1532 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever:>=38.0 (n=3096, 1532) | 2.1 (1.6 to 2.6) | 1.4 (0.9 to 2.1) | | |
| Fever: 38.0 to 38.4 deg C (n=3096, 1532) | 1.2 (0.8 to 1.6) | 0.7 (0.3 to 1.2) | | |
| Fever: >38.4 to 38.9 deg C (n=3096, 1532) | 0.7 (0.4 to 1.1) | 0.6 (0.3 to 1.1) | | |
| Fever: >38.9 to 40.0 deg C (n=3096, 1532) | 0.1 (0.0 to 0.3) | 0.1 (0.0 to 0.5) | | |
| Fever: >40.0 deg C (n=3096, 1532) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.2) | | |
| Fatigue: Any (n=3096, 1531) | 34.5 (32.8 to 36.2) | 32.4 (30.1 to 34.8) | | |

| | | | | |
|---|---|---|---|---|
| Fatigue: Mild (n=3096, 1531) | 22.7 (21.2 to 24.2) | 21.1 (19.1 to 23.2) | | |
| Fatigue: Moderate (n=3096, 1531) | 11.6 (10.5 to 12.8) | 11.2 (9.6 to 12.9) | | |
| Fatigue: Severe (n=3096, 1531) | 0.2 (0.1 to 0.4) | 0.1 (0.0 to 0.5) | | |
| Fatigue: Grade 4 (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Headache: Any (n=3096, 1531) | 22.7 (21.2 to 24.2) | 24.3 (22.2 to 26.5) | | |
| Headache: Mild (n=3096, 1531) | 17.1 (15.8 to 18.5) | 18.0 (16.1 to 20.0) | | |
| Headache: Moderate (n=3096, 1531) | 5.5 (4.7 to 6.4) | 5.9 (4.8 to 7.2) | | |
| Headache: Severe (n=3096, 1531) | 0.1 (0.0 to 0.3) | 0.4 (0.1 to 0.9) | | |
| Headache: Grade 4 (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Chills: Any (n=3096, 1531) | 5.6 (4.8 to 6.5) | 5.5 (4.4 to 6.7) | | |
| Chills: Mild (n=3096, 1531) | 4.5 (3.8 to 5.2) | 4.5 (3.5 to 5.7) | | |
| Chills: Moderate (n=3096, 1531) | 1.2 (0.8 to 1.6) | 1.0 (0.5 to 1.6) | | |
| Chills: Severe (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Chills: Grade 4 (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Vomiting: Any (n=3096, 1531) | 2.0 (1.6 to 2.6) | 2.0 (1.3 to 2.8) | | |
| Vomiting: Mild (n=3096, 1531) | 1.7 (1.3 to 2.2) | 1.8 (1.2 to 2.6) | | |
| Vomiting: Moderate (n=3096, 1531) | 0.4 (0.2 to 0.6) | 0.1 (0.0 to 0.5) | | |
| Vomiting: Severe (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Vomiting: Grade 4 (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Diarrhea: Any (n=3096, 1531) | 6.4 (5.6 to 7.3) | 4.9 (3.9 to 6.1) | | |
| Diarrhea: Mild (n=3096, 1531) | 5.9 (5.1 to 6.8) | 4.7 (3.7 to 5.9) | | |
| Diarrhea: Moderate (n=3096, 1531) | 0.5 (0.2 to 0.8) | 0.2 (0.0 to 0.6) | | |
| Diarrhea: Severe (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Diarrhea: Grade 4 (n=3096, 1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| New or worsened muscle pain: Any(n=3096,1531) | 9.3 (8.3 to 10.4) | 8.2 (6.9 to 9.7) | | |
| New or worsened muscle pain: Mild(n=3096,1531) | 6.7 (5.8 to 7.6) | 6.3 (5.1 to 7.6) | | |
| New or worsened muscle pain: Moderate(n=3096,1531) | 2.6 (2.1 to 3.3) | 2.0 (1.3 to 2.8) | | |
| New or worsened muscle pain: Severe(n=3096,1531) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.2) | | |
| New or worsened muscle pain:G4 (n=3096,1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| New or worsened joint pain:Any (n=3096,1531) | 3.4 (2.8 to 4.1) | 4.6 (3.6 to 5.7) | | |
| New or worsened joint pain:Mild (n=3096,1531) | 2.3 (1.8 to 2.9) | 3.7 (2.8 to 4.7) | | |
| New or worsened joint pain:Moderate(n=3096,1531) | 1.1 (0.8 to 1.6) | 0.9 (0.5 to 1.5) | | |
| New or worsened joint pain:Severe (n=3096,1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| New or worsened joint pain: G4 (n=3096,1531) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days

## After Dose 2: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=5 to <12 Years of age[57] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments upto Day 7 after Dose 2. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain &joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 h,moderate:>2 times in 24 h, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events: ER visit/hospitalisation & were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population was used. 'N= participants evaluable for this endpoint & 'n'= participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[57] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3064 | 1522 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: Any (n=3064, 1522) | 6.3 (5.5 to 7.2) | 1.4 (0.9 to 2.1) | | |
| Fever: >=38.0 to 38.4 deg C (n=3064, 1522) | 3.3 (2.7 to 4.0) | 0.9 (0.5 to 1.5) | | |
| Fever: >38.4 to 38.9 deg C (n=3064, 1522) | 2.3 (1.8 to 2.9) | 0.3 (0.1 to 0.8) | | |
| Fever: >38.9 to 40.0 deg C (n=3064,1522) | 0.7 (0.4 to 1.0) | 0.2 (0.0 to 0.6) | | |
| Fever: >40.0 deg C (n=3064, 1522) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.2) | | |
| Fatigue: Any (n=3064, 1521) | 39.2 (37.4 to 40.9) | 25.2 (23.0 to 27.4) | | |
| Fatigue: Mild (n=3064, 1521) | 21.7 (20.3 to 23.2) | 15.1 (13.4 to 17.0) | | |
| Fatigue: Moderate (n=3064, 1521) | 16.6 (15.3 to 17.9) | 9.8 (8.3 to 11.4) | | |
| Fatigue: Severe (n=3064, 1521) | 0.9 (0.6 to 1.3) | 0.3 (0.1 to 0.7) | | |
| Fatigue: Grade 4 (n=3064, 1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Headache: Any (n=3064, 1521) | 28.4 (26.8 to 30.0) | 18.7 (16.7 to 20.7) | | |
| Headache: Mild (n=3064, 1521) | 18.8 (17.4 to 20.2) | 13.2 (11.6 to 15.0) | | |
| Headache: Moderate (n=3064, 1521) | 9.3 (8.3 to 10.4) | 5.4 (4.3 to 6.6) | | |
| Headache: Severe (n=3064, 1521) | 0.3 (0.1 to 0.5) | 0.1 (0.0 to 0.4) | | |
| Headache: Grade 4 (n=3064, 1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Chills: Any (n=3064, 1521) | 9.8 (8.8 to 10.9) | 4.3 (3.4 to 5.5) | | |
| Chills: Mild (n=3064, 1521) | 6.7 (5.8 to 7.6) | 3.4 (2.6 to 4.5) | | |
| Chills: Moderate (n=3064, 1521) | 3.1 (2.5 to 3.7) | 0.9 (0.5 to 1.5) | | |
| Chills: Severe (n=3064, 1521) | 0.1 (0.0 to 0.2) | 0.1 (0.0 to 0.4) | | |

| | | | | |
|---|---|---|---|---|
| Chills: Grade 4 (n=3064, 1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Vomiting: Any (n=3064, 1521) | 2.0 (1.6 to 2.6) | 1.8 (1.2 to 2.6) | | |
| Vomiting: Mild (n=3064, 1521) | 1.8 (1.4 to 2.4) | 1.4 (0.9 to 2.2) | | |
| Vomiting: Moderate (n=3064, 1521) | 0.2 (0.1 to 0.4) | 0.3 (0.1 to 0.8) | | |
| Vomiting: Severe (n=3064, 1521) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.2) | | |
| Vomiting: Grade 4 (n=3064, 1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| Diarrhea: Any (n=3064, 1521) | 5.4 (4.6 to 6.3) | 5.0 (4.0 to 6.2) | | |
| Diarrhea: Mild (n=3064, 1521) | 4.9 (4.1 to 5.7) | 4.6 (3.6 to 5.8) | | |
| Diarrhea: Moderate (n=3064, 1521) | 0.5 (0.3 to 0.8) | 0.4 (0.1 to 0.9) | | |
| Diarrhea: Severe (n=3064, 1521) | 0.1 (0.0 to 0.2) | 0 (0.0 to 0.2) | | |
| Diarrhea: Grade 4 (n=3064, 1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| New or worsened muscle pain:Any (n=3064,1521) | 12.0 (10.9 to 13.2) | 6.8 (5.6 to 8.2) | | |
| New or worsened muscle pain:Mild (n=3064,1521) | 8.0 (7.1 to 9.0) | 4.5 (3.5 to 5.6) | | |
| New or worsened muscle pain: Moderate(n=3064,1521) | 4.0 (3.3 to 4.7) | 2.4 (1.7 to 3.3) | | |
| New or worsened muscle pain: Severe(n=3064,1521) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.2) | | |
| New or worsened muscle pain:G4 (n=3064,1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| New or worsened joint pain:Any (n=3064,1521) | 5.2 (4.4 to 6.0) | 3.7 (2.9 to 4.8) | | |
| New or worsened joint pain:Mild (n=3064,1521) | 3.4 (2.8 to 4.1) | 2.8 (2.0 to 3.7) | | |
| New or worsened joint pain: Moderate(n=3064,1521) | 1.8 (1.4 to 2.4) | 1.0 (0.6 to 1.6) | | |
| New or worsened joint pain: Severe (n=3064,1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |
| New or worsened joint pain:G4 (n=3064,1521) | 0 (0.0 to 0.1) | 0 (0.0 to 0.2) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=5 to <12 Years of age[58] |
|---|---|

End point description:

Systemic events were recorded in an e-diary and at unscheduled clinical assessments upto Day 7 after Dose 3. Fever: oral temperature >= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C,>38.9 to 40.0 deg C and >40.0 deg C.Fatigue,headache,chills,new or worsened muscle pain &joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild:1-2 times in 24 h,moderate:>2 times in 24 h, severe: required intravenous hydration. Diarrhea: mild: 2-3 loose stools in 24h,moderate:4-5 loose stools in 24h,severe:6 or more loose stools in 24h.G4 for all events: ER visit/hospitalisation & were classified by investigator or medically qualified person.Events reported as AEs in the CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population was used. 'N= participants evaluable for this endpoint & 'n'= participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[58] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 2265 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 | 6.8 (5.8 to 7.9) | | | |
| Fever:38.0 to 38.4 deg C | 4.1 (3.3 to 5.0) | | | |
| Fever: >38.4 to 38.9 deg C | 1.8 (1.3 to 2.4) | | | |
| Fever: >38.9 to 40.0 deg C | 0.9 (0.5 to 1.4) | | | |
| Fever: >40.0 deg C | 0.0 (0.0 to 0.2) | | | |
| Fatigue: Any | 39.6 (37.6 to 41.7) | | | |
| Fatigue: Mild | 21.0 (19.4 to 22.8) | | | |
| Fatigue: Moderate | 17.3 (15.8 to 18.9) | | | |
| Fatigue: Severe | 1.3 (0.9 to 1.8) | | | |
| Fatigue: Grade 4 | 0 (0.0 to 0.2) | | | |
| Headache: Any | 26.9 (25.1 to 28.8) | | | |
| Headache: Mild | 16.2 (14.7 to 17.8) | | | |
| Headache: Moderate | 10.3 (9.1 to 11.7) | | | |
| Headache: Severe | 0.4 (0.2 to 0.8) | | | |
| Headache: Grade 4 | 0 (0.0 to 0.2) | | | |
| Chills: Any | 10.2 (9.0 to 11.5) | | | |
| Chills: Mild | 6.2 (5.2 to 7.3) | | | |
| Chills: Moderate | 3.9 (3.1 to 4.8) | | | |
| Chills: Severe | 0.1 (0.0 to 0.4) | | | |
| Chills: Grade 4 | 0 (0.0 to 0.2) | | | |
| Vomiting: Any | 2.7 (2.1 to 3.4) | | | |
| Vomiting: Mild | 2.2 (1.6 to 2.9) | | | |
| Vomiting: Moderate | 0.4 (0.2 to 0.8) | | | |
| Vomiting: Severe | 0.0 (0.0 to 0.2) | | | |
| Vomiting: Grade 4 | 0 (0.0 to 0.2) | | | |
| Diarrhea: Any | 4.6 (3.8 to 5.5) | | | |
| Diarrhea: Mild | 4.3 (3.5 to 5.2) | | | |
| Diarrhea: Moderate | 0.3 (0.1 to 0.6) | | | |
| Diarrhea: Severe | 0.0 (0.0 to 0.2) | | | |
| Diarrhea: Grade 4 | 0 (0.0 to 0.2) | | | |
| New or worsened muscle pain: Any | 15.5 (14.0 to 17.0) | | | |
| New or worsened muscle pain: Mild | 8.8 (7.7 to 10.0) | | | |
| New or worsened muscle pain: Moderate | 6.5 (5.6 to 7.6) | | | |

| | | | | |
|---|---|---|---|---|
| New or worsened muscle pain: Severe | 0.1 (0.0 to 0.4) | | | |
| New or worsened muscle pain: Grade 4 | 0 (0.0 to 0.2) | | | |
| New or worsened joint pain: Any | 5.7 (4.8 to 6.7) | | | |
| New or worsened joint pain: Mild | 3.5 (2.8 to 4.3) | | | |
| New or worsened joint pain: Moderate | 2.2 (1.6 to 2.9) | | | |
| New or worsened joint pain: Severe | 0.0 (0.0 to 0.2) | | | |
| New or worsened joint pain: Grade 4 | 0 (0.0 to 0.2) | | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=2 to <5 Years of age[59] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[59] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2327 | 1164 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (2327, 1164) | 9.0 (7.9 to 10.3) | 8.4 (6.9 to 10.2) | | |
| Redness: Mild (2327, 1164) | 7.7 (6.7 to 8.9) | 7.5 (6.0 to 9.1) | | |
| Redness: Moderate (2327, 1164) | 1.2 (0.8 to 1.8) | 0.9 (0.4 to 1.6) | | |
| Redness: Severe (2327, 1164) | 0.0 (0.0 to 0.2) | 0.1 (0.0 to 0.5) | | |
| Redness: Grade 4 (2327, 1164) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Swelling: Any (2327, 1164) | 3.9 (3.2 to 4.8) | 3.1 (2.2 to 4.3) | | |
| Swelling: Mild (2327, 1164) | 3.4 (2.7 to 4.3) | 2.5 (1.7 to 3.6) | | |
| Swelling: Moderate (2327, 1164) | 0.5 (0.2 to 0.8) | 0.6 (0.2 to 1.2) | | |
| Swelling: Severe (2327, 1164) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Swelling: Grade 4 (2327, 1164) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |

| | | | | |
|---|---|---|---|---|
| Pain at the injection site: Any (2305, 1159) | 30.3 (28.4 to 32.2) | 20.6 (18.3 to 23.1) | | |
| Pain at the injection site: Mild (2305, 1159) | 28.1 (26.3 to 30.0) | 19.4 (17.2 to 21.8) | | |
| Pain at the injection site: Moderate (2305, 1159) | 2.2 (1.6 to 2.8) | 1.1 (0.6 to 1.9) | | |
| Pain at the injection site: Severe (2305, 1159) | 0 (0.0 to 0.2) | 0.1 (0.0 to 0.5) | | |
| Pain at the injection site: Grade 4 (2305, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.5) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=2 to <5 Years of age[60] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[60] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2094 | 1038 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (2094, 1038) | 11.2 (9.9 to 12.7) | 5.4 (4.1 to 6.9) | | |
| Redness: Mild (2094, 1038) | 9.6 (8.3 to 10.9) | 4.6 (3.4 to 6.1) | | |
| Redness: Moderate (2094, 1038) | 1.6 (1.1 to 2.3) | 0.8 (0.3 to 1.5) | | |
| Redness: Severe (2094, 1038) | 0.0 (0.0 to 0.3) | 0 (0.0 to 0.4) | | |
| Redness: Grade 4 (2094, 1038) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Swelling: Any (2094, 1038) | 5.6 (4.7 to 6.7) | 2.0 (1.3 to 3.1) | | |
| Swelling: Mild (2094, 1038) | 4.4 (3.6 to 5.4) | 1.8 (1.1 to 2.8) | | |
| Swelling: Moderate (2094, 1038) | 1.2 (0.8 to 1.8) | 0.2 (0.0 to 0.7) | | |

| | | | | |
|---|---|---|---|---|
| Swelling: Severe (2094, 1038) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Swelling: Grade 4 (2094, 1038) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Pain at the injection site: Any (2082, 1037) | 30.5 (28.5 to 32.5) | 20.3 (17.9 to 22.9) | | |
| Pain at the injection site: Mild (2082, 1037) | 28.2 (26.3 to 30.2) | 19.4 (17.0 to 21.9) | | |
| Pain at the injection site: Moderate (2082, 1037) | 2.2 (1.6 to 2.9) | 0.9 (0.4 to 1.6) | | |
| Pain at the injection site: Severe (2082, 1037) | 0 (0.0 to 0.2) | 0.1 (0.0 to 0.5) | | |
| Pain at the injection site: Grade 4 (2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=2 to <5 Years of age[61] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Redness and swelling were measured and recorded in mdu where, 1 mdu =0.5 cm and were graded as mild(>=0.5 to 2.0 cm),moderate(>2.0 to 7.0 cm),severe(>7.0 cm)& G4 (necrosis[redness and swelling]or exfoliative dermatitis[redness]).Pain at injection site was graded as mild(did not interfere with activity),moderate (interfered with activity),severe (prevented daily activity)&G4 ER visit or hospitalisation.G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination also included.Two-sided 95% CI was based on Clopper and Pearson method.Safety population=all participants who received at least 1 dose of study intervention.'N' signifies participants evaluable for this endpoint and 'n' signifies participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 799 | 376 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (799, 376) | 10.4 (8.4 to 12.7) | 4.8 (2.9 to 7.5) | | |
| Redness: Mild (799, 376) | 9.0 (7.1 to 11.2) | 4.0 (2.2 to 6.5) | | |
| Redness: Moderate (799, 376) | 1.4 (0.7 to 2.4) | 0.8 (0.2 to 2.3) | | |
| Redness: Severe (799, 376) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Redness: Grade 4 (799, 376) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Swelling: Any (799, 376) | 3.1 (2.0 to 4.6) | 1.6 (0.6 to 3.4) | | |

| | | | | |
|---|---|---|---|---|
| Swelling: Mild (799, 376) | 2.9 (1.8 to 4.3) | 1.6 (0.6 to 3.4) | | |
| Swelling: Moderate (799, 376) | 0.3 (0.0 to 0.9) | 0 (0.0 to 1.0) | | |
| Swelling: Severe (799, 376) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Swelling: Grade 4 (799, 376) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Pain at the injection site: Any (793, 375) | 28.0 (24.9 to 31.3) | 12.8 (9.6 to 16.6) | | |
| Pain at the injection site: Mild (793, 375) | 26.0 (23.0 to 29.2) | 12.0 (8.9 to 15.7) | | |
| Pain at the injection site: Moderate (793, 375) | 2.0 (1.2 to 3.3) | 0.8 (0.2 to 2.3) | | |
| Pain at the injection site: Severe (793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Pain at the injection site: Grade 4 (793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=2 to <5 Years of age[62] |
|---|---|

End point description:

Systemic events were recorded in an e-diary & at unscheduled clinical assessments from Day 1 to Day 7 after Dose 1.Fever:oral temperature>= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Fatigue,headache,chills,new or worsened muscle pain and joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild: 1-2 times in 24 h,moderate:>2 times in 24 h, severe:required intravenous hydration.Diarrhea:mild:2-3 loose stools in 24 h,moderate:4-5 loose stools in 24 h,severe:6 or more loose stools in 24 h.G4 for all events: ER visit or hospitalisation& were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population.N=participants evaluable for endpoint & n=participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[62] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2325 | 1164 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever:>=38.0(n=2325, 1164) | 5.5 (4.6 to 6.5) | 5.7 (4.4 to 7.2) | | |
| Fever: 38.0 to 38.4 deg C (n=2325, 1164) | 3.1 (2.4 to 3.8) | 2.6 (1.7 to 3.7) | | |
| Fever: >38.4 to 38.9 deg C (n=2325, 1164) | 1.5 (1.0 to 2.0) | 2.1 (1.3 to 3.1) | | |

| | | | | |
|---|---|---|---|---|
| Fever: >38.9 to 40.0 deg C (n=2325, 1164) | 0.9 (0.6 to 1.4) | 1.0 (0.5 to 1.8) | | |
| Fever: >40.0 deg C (n=2325, 1164) | 0.1 (0.0 to 0.3) | 0 (0.0 to 0.3) | | |
| Fatigue: Any (n=2304, 1159) | 30.6 (28.7 to 32.5) | 31.9 (29.2 to 34.7) | | |
| Fatigue: Mild (n=2304, 1159) | 18.8 (17.2 to 20.4) | 19.5 (17.3 to 21.9) | | |
| Fatigue: Moderate (n=2304, 1159) | 11.5 (10.2 to 12.8) | 11.6 (9.9 to 13.6) | | |
| Fatigue: Severe (n=2304, 1159) | 0.4 (0.2 to 0.7) | 0.8 (0.4 to 1.5) | | |
| Fatigue: Grade 4 (n=2304, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Headache: Any (n=2304, 1159) | 5.1 (4.2 to 6.1) | 4.8 (3.7 to 6.2) | | |
| Headache: Mild (n=2304, 1159) | 3.9 (3.2 to 4.8) | 3.7 (2.7 to 5.0) | | |
| Headache: Moderate (n=2304, 1159) | 1.1 (0.7 to 1.6) | 1.0 (0.5 to 1.8) | | |
| Headache: Severe (n=2304, 1159) | 0 (0.0 to 0.2) | 0.1 (0.0 to 0.5) | | |
| Headache: Grade 4 (n=2304, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Chills: Any (n=2304, 1159) | 2.8 (2.1 to 3.5) | 2.9 (2.0 to 4.1) | | |
| Chills: Mild (n=2304, 1159) | 1.8 (1.3 to 2.4) | 2.0 (1.3 to 3.0) | | |
| Chills: Moderate (n=2304, 1159) | 0.9 (0.5 to 1.3) | 0.9 (0.4 to 1.6) | | |
| Chills: Severe (n=2304, 1159) | 0.1 (0.0 to 0.4) | 0.1 (0.0 to 0.5) | | |
| Chills: Grade 4 (n=2304, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Vomiting: Any (n=2304, 1159) | 3.5 (2.8 to 4.4) | 2.9 (2.0 to 4.1) | | |
| Vomiting: Mild (n=2304, 1159) | 2.9 (2.2 to 3.6) | 2.1 (1.3 to 3.1) | | |
| Vomiting: Moderate (n=2304, 1159) | 0.7 (0.4 to 1.1) | 0.9 (0.4 to 1.6) | | |
| Vomiting: Severe (n=2304, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Vomiting: Grade 4 (n=2304, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Diarrhea: Any (n=2304, 1159) | 8.6 (7.4 to 9.8) | 8.3 (6.8 to 10.0) | | |
| Diarrhea: Mild (n=2304, 1159) | 7.9 (6.8 to 9.0) | 7.4 (6.0 to 9.1) | | |
| Diarrhea: Moderate (n=2304, 1159) | 0.7 (0.4 to 1.1) | 0.9 (0.4 to 1.6) | | |
| Diarrhea: Severe (n=2304, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| Diarrhea: Grade 4 (n=2304, 1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| New or worsened muscle pain:Any (n=2304,1159) | 2.6 (2.0 to 3.3) | 2.3 (1.5 to 3.4) | | |
| New or worsened muscle pain: Mild (n=2304,1159) | 1.9 (1.4 to 2.6) | 1.7 (1.1 to 2.7) | | |
| New or worsened muscle pain: Moderate(n=2304,1159) | 0.7 (0.4 to 1.1) | 0.5 (0.2 to 1.1) | | |
| New or worsened muscle pain: Severe(n=2304,1159) | 0.0 (0.0 to 0.2) | 0.1 (0.0 to 0.5) | | |
| New or worsened muscle pain: G4(n=2304,1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| New or worsened joint pain: Any (n=2304,1159) | 1.2 (0.8 to 1.7) | 1.8 (1.1 to 2.8) | | |
| New or worsened joint pain:Mild (n=2304,1159) | 0.9 (0.6 to 1.4) | 1.4 (0.8 to 2.2) | | |
| New or worsened joint pain: Moderate(n=2304,1159) | 0.2 (0.1 to 0.5) | 0.4 (0.1 to 1.0) | | |
| New or worsened joint pain:Severe (n=2304,1159) | 0.0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |
| New or worsened joint pain: G4 (n=2304,1159) | 0 (0.0 to 0.2) | 0 (0.0 to 0.3) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=2 to <5 Years of age[63] |
|---|---|

End point description:

Systemic events were recorded in an e-diary & at unscheduled clinical assessments from Day 1 to Day 7 after Dose 2.Fever:oral temperature>= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Fatigue,headache,chills,new or worsened muscle pain and joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild: 1-2 times in 24 h,moderate:>2 times in 24 h, severe:required intravenous hydration.Diarrhea:mild:2-3 loose stools in 24 h,moderate:4-5 loose stools in 24 h,severe:6 or more loose stools in 24 h.G4 for all events: ER visit or hospitalisation& were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population.N=participants evaluable for endpoint & n=participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[63] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2094 | 1038 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 (n=2094, 1038) | 5.2 (4.3 to 6.2) | 5.8 (4.4 to 7.4) | | |
| Fever:38.0 to 38.4 deg C (n=2094, 1038) | 2.4 (1.8 to 3.2) | 2.2 (1.4 to 3.3) | | |
| Fever: >38.4 to 38.9 deg C (n=2094, 1038) | 1.5 (1.0 to 2.2) | 2.6 (1.7 to 3.8) | | |
| Fever: >38.9 to 40.0 deg C (n=2094, 1038) | 1.1 (0.7 to 1.6) | 0.9 (0.4 to 1.6) | | |
| Fever: >40.0 deg C (n=2094, 1038) | 0.1 (0.0 to 0.4) | 0.1 (0.0 to 0.5) | | |
| Fatigue: Any (n=2082, 1037) | 26.1 (24.2 to 28.0) | 24.3 (21.7 to 27.0) | | |
| Fatigue: Mild (n=2082, 1037) | 15.5 (13.9 to 17.1) | 14.7 (12.6 to 17.0) | | |
| Fatigue: Moderate (n=2082, 1037) | 10.2 (9.0 to 11.6) | 9.3 (7.6 to 11.2) | | |
| Fatigue: Severe (n=2082, 1037) | 0.4 (0.2 to 0.8) | 0.4 (0.1 to 1.0) | | |
| Fatigue: Grade 4 (n=2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Headache: Any (n=2082, 1037) | 4.6 (3.8 to 5.6) | 4.1 (3.0 to 5.5) | | |
| Headache: Mild (n=2082, 1037) | 3.5 (2.7 to 4.3) | 2.6 (1.7 to 3.8) | | |
| Headache: Moderate (n=2082, 1037) | 1.2 (0.7 to 1.7) | 1.4 (0.8 to 2.4) | | |
| Headache: Severe (n=2082, 1037) | 0 (0.0 to 0.2) | 0.1 (0.0 to 0.5) | | |
| Headache: Grade 4 (n=2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Chills: Any (n=2082, 1037) | 3.2 (2.5 to 4.0) | 2.8 (1.9 to 4.0) | | |
| Chills: Mild (n=2082, 1037) | 2.2 (1.6 to 2.9) | 2.2 (1.4 to 3.3) | | |
| Chills: Moderate (n=2082, 1037) | 1.0 (0.6 to 1.5) | 0.6 (0.2 to 1.3) | | |

| | | | | |
|---|---|---|---|---|
| Chills: Severe (n=2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Chills: Grade 4 (n=2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Vomiting: Any (n=2082, 1037) | 3.4 (2.6 to 4.2) | 3.4 (2.4 to 4.7) | | |
| Vomiting: Mild (n=2082, 1037) | 3.0 (2.3 to 3.8) | 2.9 (2.0 to 4.1) | | |
| Vomiting: Moderate (n=2082, 1037) | 0.4 (0.2 to 0.8) | 0.5 (0.2 to 1.1) | | |
| Vomiting: Severe (n=2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Vomiting: Grade 4 (n=2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| Diarrhea: Any (n=2082, 1037) | 6.8 (5.7 to 7.9) | 8.0 (6.4 to 9.8) | | |
| Diarrhea: Mild (n=2082, 1037) | 5.9 (4.9 to 7.0) | 7.1 (5.6 to 8.9) | | |
| Diarrhea: Moderate (n=2082, 1037) | 0.8 (0.5 to 1.3) | 0.8 (0.3 to 1.5) | | |
| Diarrhea: Severe (n=2082, 1037) | 0.1 (0.0 to 0.3) | 0.1 (0.0 to 0.5) | | |
| Diarrhea: Grade 4 (n=2082, 1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| New or worsened muscle pain: Any (n=2082, 1037) | 2.6 (2.0 to 3.4) | 2.6 (1.7 to 3.8) | | |
| New or worsened muscle pain:Mild (n=2082,1037) | 1.9 (1.3 to 2.6) | 2.0 (1.3 to 3.1) | | |
| New or worsened muscle pain: Moderate(n=2082,1037) | 0.8 (0.4 to 1.2) | 0.6 (0.2 to 1.3) | | |
| New or worsened muscle pain: Severe(n=2082,1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| New or worsened muscle pain: G4 (n=2082,1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| New or worsened joint pain:Any (n=2082,1037) | 1.2 (0.8 to 1.8) | 1.2 (0.6 to 2.0) | | |
| New or worsened joint pain:Mild (n=2082,1037) | 0.9 (0.6 to 1.4) | 0.9 (0.4 to 1.6) | | |
| New or worsened joint pain: Moderate(n=2082,1037) | 0.3 (0.1 to 0.7) | 0.3 (0.1 to 0.8) | | |
| New or worsened joint pain:Severe (n=2082,1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |
| New or worsened joint pain:G4 (n=2082,1037) | 0 (0.0 to 0.2) | 0 (0.0 to 0.4) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=2 to <5 Years of age[64] |
|---|---|

End point description:

Systemic events were recorded in an e-diary & at unscheduled clinical assessments from Day 1 to Day 7 after Dose 3.Fever:oral temperature>= 38.0 deg C;categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Fatigue,headache,chills,new or worsened muscle pain and joint pain: mild(did not interfere with activity),moderate(some interference with activity),severe(prevented daily routine activity).Vomiting:mild: 1-2 times in 24 h,moderate:>2 times in 24 h, severe:required intravenous hydration.Diarrhea:mild:2-3 loose stools in 24 h,moderate:4-5 loose stools in 24 h,severe:6 or more loose stools in 24 h.G4 for all events: ER visit or hospitalisation& were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included.Exact 95%CI based on Clopper and Pearson method. Safety population.N=participants evaluable for endpoint & n=participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[64] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 799 | 376 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 (n=799, 376) | 5.1 (3.7 to 6.9) | 5.6 (3.5 to 8.4) | | |
| Fever:38.0 to 38.4 deg C (n=799, 376) | 2.5 (1.5 to 3.8) | 2.1 (0.9 to 4.1) | | |
| Fever: >38.4 to 38.9 deg C (n=799, 376) | 1.8 (1.0 to 2.9) | 1.9 (0.8 to 3.8) | | |
| Fever: >38.9 to 40.0 deg C (n=799, 376) | 0.9 (0.4 to 1.8) | 1.6 (0.6 to 3.4) | | |
| Fever: >40.0 deg C (n=799, 376) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Fatigue: Any (n=793, 375) | 25.5 (22.5 to 28.7) | 24.3 (20.0 to 28.9) | | |
| Fatigue: Mild (n=793, 375) | 16.0 (13.5 to 18.8) | 14.7 (11.2 to 18.7) | | |
| Fatigue: Moderate (n=793, 375) | 9.2 (7.3 to 11.4) | 9.3 (6.6 to 12.7) | | |
| Fatigue: Severe (n=793, 375) | 0.3 (0.0 to 0.9) | 0.3 (0.0 to 1.5) | | |
| Fatigue: Grade 4 (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Headache: Any (n=793, 375) | 4.5 (3.2 to 6.2) | 4.0 (2.3 to 6.5) | | |
| Headache: Mild (n=793, 375) | 2.9 (1.8 to 4.3) | 2.9 (1.5 to 5.2) | | |
| Headache: Moderate (n=793, 375) | 1.6 (0.9 to 2.8) | 1.1 (0.3 to 2.7) | | |
| Headache: Severe (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Headache: Grade 4 (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Chills: Any (n=793, 375) | 2.8 (1.7 to 4.2) | 2.7 (1.3 to 4.8) | | |
| Chills: Mild (n=793, 375) | 2.1 (1.3 to 3.4) | 2.4 (1.1 to 4.5) | | |
| Chills: Moderate (n=793, 375) | 0.5 (0.1 to 1.3) | 0.3 (0.0 to 1.5) | | |
| Chills: Severe (n=793, 375) | 0.1 (0.0 to 0.7) | 0 (0.0 to 1.0) | | |
| Chills: Grade 4 (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Vomiting: Any (n=793, 375) | 2.0 (1.2 to 3.3) | 4.3 (2.5 to 6.8) | | |
| Vomiting: Mild (n=793, 375) | 1.5 (0.8 to 2.6) | 2.9 (1.5 to 5.2) | | |
| Vomiting: Moderate (n=793, 375) | 0.5 (0.1 to 1.3) | 1.3 (0.4 to 3.1) | | |
| Vomiting: Severe (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Vomiting: Grade 4 (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Diarrhea: Any (n=793, 375) | 4.9 (3.5 to 6.7) | 5.6 (3.5 to 8.4) | | |
| Diarrhea: Mild (n=793, 375) | 3.8 (2.6 to 5.4) | 4.5 (2.7 to 7.2) | | |
| Diarrhea: Moderate (n=793, 375) | 1.1 (0.5 to 2.1) | 1.1 (0.3 to 2.7) | | |
| Diarrhea: Severe (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| Diarrhea: Grade 4 (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| New or worsened muscle pain: Any (n=793, 375) | 1.9 (1.1 to 3.1) | 1.6 (0.6 to 3.4) | | |
| New or worsened muscle pain: Mild (n=793, 375) | 1.5 (0.8 to 2.6) | 1.3 (0.4 to 3.1) | | |
| New or worsened muscle pain: Moderate (n=793, 375) | 0.4 (0.1 to 1.1) | 0.3 (0.0 to 1.5) | | |
| New or worsened muscle pain: Severe (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |

| | | | | |
|---|---|---|---|---|
| New or worsened muscle pain: Grade 4 (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |
| New or worsened joint pain: Any (n=793, 375) | 1.1 (0.5 to 2.1) | 1.1 (0.3 to 2.7) | | |
| New or worsened joint pain: Mild (n=793, 375) | 0.9 (0.4 to 1.8) | 1.1 (0.3 to 2.7) | | |
| New or worsened joint pain: Moderate (n=793, 375) | 0.1 (0.0 to 0.7) | 0 (0.0 to 1.0) | | |
| New or worsened joint pain: Severe (n=793, 375) | 0.1 (0.0 to 0.7) | 0 (0.0 to 1.0) | | |
| New or worsened joint pain: Grade 4 (n=793, 375) | 0 (0.0 to 0.5) | 0 (0.0 to 1.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 1: >=6 Months to <2 Years of age[65] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 1. Redness and swelling were measured and recorded in mdu where,1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) & G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate(hurts if gently touched with crying), severe (causes limitation of limb movement) & G4 (ER visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population was used. 'N=participants evaluable for this endpoint and 'n=participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[65] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1439 | 712 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (n=1439, 712) | 10.7 (9.2 to 12.4) | 7.6 (5.7 to 9.8) | | |
| Redness: Mild (n=1439, 712) | 9.8 (8.3 to 11.5) | 7.2 (5.4 to 9.3) | | |
| Redness: Moderate (n=1439, 712) | 0.9 (0.5 to 1.5) | 0.4 (0.1 to 1.2) | | |
| Redness: Severe (n=1439, 712) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |
| Redness: Grade 4 (n=1439, 712) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |

| | | | | |
|---|---|---|---|---|
| Swelling: Any (n=1439, 712) | 3.8 (2.8 to 4.9) | 2.5 (1.5 to 4.0) | | |
| Swelling: Mild (n=1439, 712) | 3.3 (2.5 to 4.4) | 2.2 (1.3 to 3.6) | | |
| Swelling: Moderate (n=1439, 712) | 0.4 (0.2 to 0.9) | 0.3 (0.0 to 1.0) | | |
| Swelling: Severe (n=1439, 712) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |
| Swelling: Grade 4 (n=1439, 712) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |
| Tenderness at injection site: Any (n=1425, 706) | 17.2 (15.3 to 19.3) | 12.6 (10.2 to 15.3) | | |
| Tenderness at injection site: Mild (n=1425, 706) | 16.3 (14.4 to 18.3) | 11.5 (9.2 to 14.1) | | |
| Tenderness at injection site:Moderate (n=1425,706) | 0.8 (0.4 to 1.5) | 1.1 (0.5 to 2.2) | | |
| Tenderness at injection site:Severe(n=1425,706) | 0.1 (0.0 to 0.4) | 0 (0.0 to 0.5) | | |
| Tenderness at injection site: G4 (n=1425, 706) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 2: >=6 Months to <2 Years of age[66] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 2. Redness and swelling were measured and recorded in mdu where,1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) & G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate(hurts if gently touched with crying), severe (causes limitation of limb movement) & G4 (ER visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population was used. 'N=participants evaluable for this endpoint and 'n=participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[66] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1323 | 666 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Redness: Any (n= 1323,666) | 9.9 (8.3 to 11.6) | 6.3 (4.6 to 8.4) | | |
| Redness: Mild (n= 1323,666) | 9.1 (7.6 to 10.7) | 5.9 (4.2 to 7.9) | | |

| | | | | |
|---|---|---|---|---|
| Redness: Moderate (n= 1323,666) | 0.8 (0.4 to 1.5) | 0.5 (0.1 to 1.3) | | |
| Redness: Severe (n= 1323,666) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |
| Redness: Grade 4 (n= 1323,666) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |
| Swelling: Any (n= 1323,666) | 4.1 (3.1 to 5.3) | 1.5 (0.7 to 2.7) | | |
| Swelling: Mild (n= 1323,666) | 3.5 (2.6 to 4.6) | 1.4 (0.6 to 2.5) | | |
| Swelling: Moderate (n= 1323,666) | 0.6 (0.3 to 1.2) | 0.2 (0.0 to 0.8) | | |
| Swelling: Severe (n= 1323,666) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |
| Swelling: Grade 4 (n= 1323,666) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |
| Tenderness at injection site: Any(n= 1314,664) | 15.4 (13.5 to 17.5) | 9.3 (7.2 to 11.8) | | |
| Tenderness at injection site:Mild (n= 1314,664) | 13.8 (12.0 to 15.8) | 7.7 (5.8 to 10.0) | | |
| Tenderness at injection site:Moderate(n=1314,664) | 1.6 (1.0 to 2.4) | 1.7 (0.8 to 2.9) | | |
| Tenderness at injection site:Severe (n= 1314,664) | 0.1 (0.0 to 0.4) | 0 (0.0 to 0.6) | | |
| Tenderness at injection site: G4 (n= 1314,664) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants With Local Reactions Within 7 Days After Dose 3: >=6 Months to <2 Years of age[67] |
|---|---|

End point description:

Local reactions were collected in e-diary or during unscheduled clinical assessments from Day 1 to Day 7 after Dose 3. Redness and swelling were measured and recorded in mdu where,1 mdu =0.5 cm and were graded as mild (>=0.5 to 2.0 cm), moderate (>2.0 to 7.0 cm), severe (>7.0 cm) & G4 (necrosis [redness and swelling] or exfoliative dermatitis [redness]). Tenderness at injection site was graded as mild (hurts if gently touched), moderate(hurts if gently touched with crying), severe (causes limitation of limb movement) & G4 (ER visit or hospitalisation).G4 were classified by investigator or medically qualified person. Reactions reported as adverse events in case report form within 7 days of study vaccination were also included. Two-sided 95% CI was based on Clopper and Pearson method. Safety population was used. 'N=participants evaluable for this endpoint and 'n=participants evaluable for the specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[67] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 459 | 222 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |

| | | | | |
|---|---|---|---|---|
| Redness: Any (n=459,222) | 7.2 (5.0 to 9.9) | 5.0 (2.5 to 8.7) | | |
| Redness: Mild (n=459,222) | 5.0 (3.2 to 7.4) | 4.5 (2.2 to 8.1) | | |
| Redness: Moderate (n=459,222) | 2.0 (0.9 to 3.7) | 0.5 (0.0 to 2.5) | | |
| Redness: Severe (n=459,222) | 0.2 (0.0 to 1.2) | 0 (0.0 to 1.6) | | |
| Redness: Grade 4 (n=459,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |
| Swelling: Any (n=459,222) | 3.3 (1.8 to 5.3) | 2.3 (0.7 to 5.2) | | |
| Swelling: Mild (n=459,222) | 2.0 (0.9 to 3.7) | 2.3 (0.7 to 5.2) | | |
| Swelling: Moderate (n=459,222) | 1.3 (0.5 to 2.8) | 0 (0.0 to 1.6) | | |
| Swelling: Severe (n=459,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |
| Swelling: Grade 4 (n=459,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |
| Tenderness at injection site:Any (n=455,222) | 14.7 (11.6 to 18.3) | 9.9 (6.3 to 14.6) | | |
| Tenderness at injection site:Mild (n=455,222) | 13.0 (10.0 to 16.4) | 8.6 (5.2 to 13.0) | | |
| Tenderness at injection site: Moderate(n=455,222) | 1.8 (0.8 to 3.4) | 1.4 (0.3 to 3.9) | | |
| Tenderness at injection site:Severe (n=455,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |
| Tenderness at injection site: G4 (n=455,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 1: >=6 Months to <2 Years of age[68] |
|---|---|

End point description:

Systemic events recorded in an e-diary & at unscheduled clinical assessments up to Day 7 after Dose 1. Fever: oral temperature >= 38.0 deg C; categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Decreased appetite: mild (decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed). Drowsiness: mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit or hospitalisation & were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. N=participants evaluable for this endpoint & n=participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 1

Notes:

[68] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1439 | 712 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 (n=1439,712) | 7.2 (5.9 to 8.7) | 7.4 (5.6 to 9.6) | | |
| Fever: 38.0 to 38.4 deg C (n=1439,712) | 3.4 (2.5 to 4.5) | 3.5 (2.3 to 5.1) | | |
| Fever: >38.4 to 38.9 deg C (n=1439,712) | 2.2 (1.5 to 3.1) | 2.5 (1.5 to 4.0) | | |
| Fever: >38.9 to 40.0 deg C (n=1439,712) | 1.5 (1.0 to 2.3) | 1.3 (0.6 to 2.4) | | |
| Fever: >40.0 deg C (n=1439,712) | 0.1 (0.0 to 0.4) | 0.1 (0.0 to 0.8) | | |
| Decreased appetite: Any (n=1425,706) | 22.7 (20.5 to 24.9) | 21.2 (18.3 to 24.5) | | |
| Decreased appetite: Mild (n=1425,706) | 12.4 (10.7 to 14.2) | 12.0 (9.7 to 14.7) | | |
| Decreased appetite: Moderate (n=1425,706) | 10.1 (8.6 to 11.8) | 8.9 (6.9 to 11.3) | | |
| Decreased appetite: Severe (n=1425,706) | 0.2 (0.0 to 0.6) | 0.3 (0.0 to 1.0) | | |
| Decreased appetite: Grade 4 (n=1425,706) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |
| Drowsiness: Any (n=1425,706) | 27.8 (25.5 to 30.2) | 30.0 (26.7 to 33.6) | | |
| Drowsiness: Mild (n=1425,706) | 22.0 (19.8 to 24.2) | 22.7 (19.6 to 25.9) | | |
| Drowsiness: Moderate (n=1425,706) | 5.6 (4.5 to 6.9) | 6.9 (5.2 to 9.1) | | |
| Drowsiness: Severe (n=1425,706) | 0.2 (0.0 to 0.6) | 0.4 (0.1 to 1.2) | | |
| Drowsiness: Grade 4 (n=1425,706) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |
| Irritability: Any (n=1425,706) | 51.0 (48.4 to 53.6) | 48.2 (44.4 to 51.9) | | |
| Irritability: Mild (n=1425,706) | 20.6 (18.6 to 22.8) | 18.3 (15.5 to 21.3) | | |
| Irritability: Moderate (n=1425,706) | 29.7 (27.3 to 32.1) | 29.6 (26.3 to 33.1) | | |
| Irritability: Severe (n=1425,706) | 0.7 (0.3 to 1.3) | 0.3 (0.0 to 1.0) | | |
| Irritability: Grade 4 (n=1425,706) | 0 (0.0 to 0.3) | 0 (0.0 to 0.5) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 2: >=6 Months to <2 Years of age[69] |
|---|---|

End point description:

Systemic events recorded in an e-diary & at unscheduled clinical assessments up to Day 7 after Dose 2. Fever: oral temperature >= 38.0 deg C; categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Decreased appetite: mild (decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed). Drowsiness: mild(increased or

bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit or hospitalisation & were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. N=participants evaluable for this endpoint & n=participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 2

Notes:

[69] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1322 | 666 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever: >=38.0 (n=1322,666) | 7.6 (6.3 to 9.2) | 6.5 (4.7 to 8.6) | | |
| Fever: 38.0 to 38.4 deg C (n=1322,666) | 3.6 (2.7 to 4.8) | 3.6 (2.3 to 5.3) | | |
| Fever: >38.4 to 38.9 deg C (n=1322,666) | 2.0 (1.4 to 3.0) | 1.7 (0.8 to 2.9) | | |
| Fever: >38.9 to 40.0 deg C (n=1322,666) | 1.9 (1.2 to 2.8) | 1.2 (0.5 to 2.4) | | |
| Fever: >40.0 deg C (n=1322,666) | 0.1 (0.0 to 0.4) | 0 (0.0 to 0.6) | | |
| Decreased appetite: Any (n=1314,664) | 22.5 (20.3 to 24.9) | 19.4 (16.5 to 22.6) | | |
| Decreased appetite: Mild (n=1314,664) | 13.9 (12.1 to 15.9) | 11.3 (9.0 to 14.0) | | |
| Decreased appetite: Moderate (n=1314,664) | 8.1 (6.7 to 9.8) | 8.0 (6.0 to 10.3) | | |
| Decreased appetite: Severe (n=1314,664) | 0.5 (0.2 to 1.0) | 0.2 (0.0 to 0.8) | | |
| Decreased appetite: Grade 4 (n=1314,664) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |
| Drowsiness: Any (n=1314,664) | 24.1 (21.8 to 26.5) | 21.4 (18.3 to 24.7) | | |
| Drowsiness: Mild (n=1314,664) | 17.8 (15.8 to 20.0) | 16.9 (14.1 to 19.9) | | |
| Drowsiness: Moderate (n=1314,664) | 6.0 (4.8 to 7.4) | 4.4 (2.9 to 6.2) | | |
| Drowsiness: Severe (n=1314,664) | 0.3 (0.1 to 0.8) | 0.2 (0.0 to 0.8) | | |
| Drowsiness: Grade 4 (n=1314,664) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |
| Irritability: Any (n=1314,664) | 46.9 (44.2 to 49.6) | 41.4 (37.6 to 45.3) | | |
| Irritability: Mild (n=1314,664) | 18.5 (16.4 to 20.7) | 15.8 (13.1 to 18.8) | | |
| Irritability: Moderate (n=1314,664) | 27.8 (25.4 to 30.3) | 24.7 (21.5 to 28.2) | | |
| Irritability: Severe (n=1314,664) | 0.6 (0.3 to 1.2) | 0.9 (0.3 to 2.0) | | |
| Irritability: Grade 4 (n=1314,664) | 0 (0.0 to 0.3) | 0 (0.0 to 0.6) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants With Systemic Events Within 7 Days After Dose 3: >=6 Months to <2 Years of age[70] |
|---|---|

End point description:

Systemic events recorded in an e-diary & at unscheduled clinical assessments up to Day 7 after Dose 3. Fever: oral temperature >= 38.0 deg C; categorised as >=38.0 to 38.4 deg C,>38.4 to 38.9 deg C, >38.9 to 40.0 deg C & >40.0 deg C. Decreased appetite: mild (decreased interest in eating),moderate(decreased oral intake),severe(refusal to feed). Drowsiness: mild(increased or prolonged sleeping bouts),moderate(slightly subdued interfering with daily activity),severe(disabling;not interested in usual daily activity).Irritability:mild(easily consolable),moderate(requiring increased attention),severe(Inconsolable; crying cannot be comforted).G4 for all events: ER visit or hospitalisation & were classified by investigator or medically qualified person. Events reported as AEs in CRF within 7 days after vaccination were also included. Exact 95% CI based on Clopper and Pearson method. Safety population. N=participants evaluable for this endpoint & n=participants evaluable for specified rows.

| End point type | Primary |
|---|---|

End point timeframe:

Day 1 to Day 7 after Dose 3

Notes:

[70] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 459 | 222 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Fever:>=38.0 (n=459,222) | 6.1 (4.1 to 8.7) | 5.9 (3.2 to 9.8) | | |
| Fever:38.0 to 38.4 deg C (n=459,222) | 3.3 (1.8 to 5.3) | 3.2 (1.3 to 6.4) | | |
| Fever: >38.4 to 38.9 deg C (n=459,222) | 1.3 (0.5 to 2.8) | 1.8 (0.5 to 4.5) | | |
| Fever: >38.9 to 40.0 deg C (n=459,222) | 1.1 (0.4 to 2.5) | 0.9 (0.1 to 3.2) | | |
| Fever: >40.0 deg C (n=459,222) | 0.4 (0.1 to 1.6) | 0 (0.0 to 1.6) | | |
| Decreased appetite: Any (n=455,222) | 19.6 (16.0 to 23.5) | 13.1 (8.9 to 18.2) | | |
| Decreased appetite: Mild (n=455,222) | 11.2 (8.5 to 14.5) | 7.2 (4.2 to 11.4) | | |
| Decreased appetite: Moderate (n=455,222) | 7.5 (5.2 to 10.3) | 5.9 (3.2 to 9.8) | | |
| Decreased appetite: Severe (n=455,222) | 0.9 (0.2 to 2.2) | 0 (0.0 to 1.6) | | |

| | | | | |
|---|---|---|---|---|
| Decreased appetite: Grade 4 (n=455,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |
| Drowsiness: Any (n=455,222) | 21.5 (17.8 to 25.6) | 12.2 (8.2 to 17.2) | | |
| Drowsiness: Mild (n=455,222) | 15.8 (12.6 to 19.5) | 9.0 (5.6 to 13.6) | | |
| Drowsiness: Moderate (n=455,222) | 5.3 (3.4 to 7.7) | 2.7 (1.0 to 5.8) | | |
| Drowsiness: Severe (n=455,222) | 0.4 (0.1 to 1.6) | 0.5 (0.0 to 2.5) | | |
| Drowsiness: Grade 4 (n=455,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |
| Irritability: Any (n=455,222) | 42.0 (37.4 to 46.7) | 36.9 (30.6 to 43.7) | | |
| Irritability: Mild (n=455,222) | 15.8 (12.6 to 19.5) | 15.3 (10.8 to 20.7) | | |
| Irritability: Moderate (n=455,222) | 25.7 (21.8 to 30.0) | 21.6 (16.4 to 27.6) | | |
| Irritability: Severe (n=455,222) | 0.4 (0.1 to 1.6) | 0 (0.0 to 1.6) | | |
| Irritability: Grade 4 (n=455,222) | 0 (0.0 to 0.8) | 0 (0.0 to 1.6) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=5 to <12 Years of age[71] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[71] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3109 | 1538 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 10.7 (9.6 to 11.9) | 9.8 (8.3 to 11.3) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3: >=5 to <12 Years of age[72] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[72] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 2408 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 8.0 (7.0 to 9.2) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : >=5 to <12 Years of age[73] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[73] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 3109 | 1538 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.3 (0.1 to 0.5) | 0.1 (0.0 to 0.5) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3: >=5 to <12 Years of age[74] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[74] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 2408 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.4 (0.2 to 0.8) | | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2: >=2 to <5 Years of age[75] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[75] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2350 | 1173 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 13.1 (11.8 to 14.6) | 13.0 (11.1 to 15.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3:>=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3:>=2 to <5 Years of age[76] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[76] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 863 | 405 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 4.5 (3.2 to 6.1) | 6.4 (4.2 to 9.3) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2: >=2 to <5 Years of age[77] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[77] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 2350 | 1173 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.5 (0.2 to 0.8) | 0.9 (0.4 to 1.6) | | |

### Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3:>=2 to <5 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3:>=2 to <5 Years of age[78] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was an important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[78] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 863 | 405 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.3 (0.1 to 1.0) | 0 (0.0 to 0.9) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2 : >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 1 to 1 Month After Dose 2 : >=6 Months to <2 Years of age[79] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 1 to 1 month after dose 2 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 1 month after Dose 2

Notes:

[79] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1447 | 718 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 21.5 (19.4 to 23.7) | 19.9 (17.1 to 23.0) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3 : >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Adverse Events From Dose 3 to 1 Month After Dose 3 : >=6 Months to <2 Years of age[80] |
|---|---|

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Percentage of participants reporting AEs after dose 3 to 1 month after dose 3 were reported in this endpoint. Exact 2-sided CI based on the Clopper and Pearson method. Only AEs collected by non-systematic assessment (i.e. excluding local reactions and systemic events) were reported in this endpoint. Safety population included all participants who received at least 1 dose of the study intervention.'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 1 month after Dose 3

Notes:

[80] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 483 | 237 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 10.4 (7.8 to 13.4) | 7.6 (4.6 to 11.7) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events

### From Dose 1 to 6 Months After Dose 2 : >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 1 to 6 Months After Dose 2 : >=6 Months to <2 Years of age[81] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 1 to 6 months after Dose 2

Notes:

[81] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1447 | 718 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 1.7 (1.1 to 2.5) | 2.4 (1.4 to 3.8) | | |

### Statistical analyses

No statistical analyses for this end point

### Primary: Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : >=6 Months to <2 Years of age

| End point title | Phase 2/3: Percentage of Participants Reporting Serious Adverse Events From Dose 3 to 6 Months After Dose 3 : >=6 Months to <2 Years of age[82] |
|---|---|

End point description:

An SAE was defined as any untoward medical occurrence that at any dose resulted in death, was life-threatening; resulted in persistent disability/incapacity; constituted a congenital anomaly/birth defect; was important medical event; required inpatient hospitalisation or prolongation of existing hospitalisation, was a suspected transmission via a Pfizer product of an infectious agent, pathogenic or non-pathogenic. Exact 2-sided 95% CI was based on the Clopper and Pearson method. Safety population included all participants who received at least 1 dose of the study intervention. 'N' signifies participants evaluable for this endpoint.

| End point type | Primary |
|---|---|

End point timeframe:

From Dose 3 to 6 months after Dose 3 (Approximately 6 months)

Notes:

[82] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was planned to be analysed only for the specified reporting arms.

| End point values | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 483 | 237 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 0.2 (0.0 to 1.1) | 0 (0.0 to 1.5) | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Phase 2/3: Geometric Mean Ratio (GMR) for SARS-CoV-2 Neutralizing Titers in Participants >=5 to <12 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study:1 Month After Dose 2:Participants Without Evidence of Infection

| End point title | Phase 2/3: Geometric Mean Ratio (GMR) for SARS-CoV-2 Neutralizing Titers in Participants >=5 to <12 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study:1 Month After Dose 2:Participants Without Evidence of Infection |
|---|---|

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

| End point type | Primary |
|---|---|

End point timeframe:

C4591007 (>=5 to <12 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

| End point values | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 264 | 253 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 1197.6 (1106.1 to 1296.6) | 1146.5 (1045.5 to 1257.2) | | |

### Statistical analyses

| Statistical analysis title | Geometric Mean Ratio |
|---|---|

Statistical analysis description:

Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers in Participants >=5 to <12 Years of age to Participants 16 to 25 Years of age from Phase 2/3 of the C4591001 Study : 1 Month after Dose 2

| | |
|---|---|
| Comparison groups | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
| Number of subjects included in analysis | 517 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Geometric mean ratio |
| Point estimate | 1.04 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.93 |
| upper limit | 1.18 |

## Primary: Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=5 to <12 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

| | |
|---|---|
| End point title | Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=5 to <12 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection |

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

C4591007 (>=5 to <12 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

| End point values | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 264 | 253 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 99.2 (97.3 to 99.9) | 99.2 (97.2 to 99.9) | | |

**Statistical analyses**

| Statistical analysis title | Difference in Percentages |
|---|---|

Statistical analysis description:

Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection up to 1 Month After Dose 2 – Immunobridging Subset – Phase 2/3 – Comparison of 5 to <12 Years of Age to Study C4591001 Phase 2/3 – 16 Through 25 Years of Age

| | |
|---|---|
| Comparison groups | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
| Number of subjects included in analysis | 517 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference in percentage |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2 |
| upper limit | 2.2 |

## Primary: Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=2 to <5 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection

| End point title | Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=2 to <5 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection |
|---|---|

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

| End point type | Primary |
|---|---|

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 243 | 252 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 763.9 (688.5 to 847.5) | 1255.4 (1131.2 to 1393.3) | | |

**Statistical analyses**

| **Statistical analysis title** | Geometric Mean Ratio |
|---|---|
| Statistical analysis description: | |
| Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers in Participants >=2 to <5 Years of age to Participants 16 to 25 Years of age from Phase 2/3 of the C4591001 study : at 1 Month after Dose- 2 Phase 2/3 | |
| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
| Number of subjects included in analysis | 495 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Geometric mean ratio |
| Point estimate | 0.61 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.53 |
| upper limit | 0.7 |

**Primary: Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=2 to <5 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection**

| End point title | Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=2 to <5 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection |
|---|---|

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a

postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

| End point type | Primary |
|---|---|

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 243 | 251 | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 96.7 (93.6 to 98.6) | 97.6 (94.9 to 99.1) | | |

## Statistical analyses

| **Statistical analysis title** | Difference in Percentage |
|---|---|

Statistical analysis description:

Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=2 to <5 Years of age and 16 to 25 Years of age from Phase 2/3 of the C4591001 study : 1 Month after Dose 2

| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
|---|---|
| Number of subjects included in analysis | 494 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference in Percentage |
| Point estimate | -0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.3 |
| upper limit | 2.3 |

**Primary: Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=6 Months to <2 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of**

## Infection

| | |
|---|---|
| End point title | Phase 2/3: GMR for SARS-CoV-2 Neutralizing Titers in Participants >=6 Months to <2 Years of age to Participants 16 to 25 Years of age From Phase 2/3 of the C4591001 Study : 1 Month After Dose 2: Participants Without Evidence of Infection |

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

C4591007 (>=6 months to <2 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 245 | 238 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 979.7 (893.2 to 1074.6) | 946.8 (850.8 to 1053.7) | | |

## Statistical analyses

| **Statistical analysis title** | Geometric Mean Ratio |
|---|---|

Statistical analysis description:

Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers in Participants >=6 Months to <2 Years of age to Participants 16 to 25 Years of age from Phase 2/3 of the C4591001 study : at 1 Month after Dose 2

| | |
|---|---|
| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
| Number of subjects included in analysis | 483 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Geometric Mean Ratio |
| Point estimate | 1.03 |

| Confidence interval | |
|---|---|
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 1.19 |

## Primary: Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=6 Months to <2 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study: 1 Month After Dose 2: Participants Without Evidence of Infection

| End point title | Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=6 Months to <2 Years of age and 16 to 25 Years of age From Phase 2/3 of the C4591001 Study: 1 Month After Dose 2: Participants Without Evidence of Infection |
|---|---|

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

| End point type | Primary |
|---|---|

End point timeframe:

C4591007 (>=6 months to <2 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 245 | 238 | | |
| Units: Percentage of Participants | | | | |
| number (confidence interval 95%) | 98.0 (95.3 to 99.3) | 96.2 (92.9 to 98.3) | | |

## Statistical analyses

| **Statistical analysis title** | Difference in Percentage |
|---|---|

Statistical analysis description:

Phase 2/3: Difference in Percentage of Participants who Achieved Seroresponse in >=6 Months to <2 Years of age and 16 to 25 Years of age from Phase 2/3 of the C4591001 study : 1 Month after Dose 2

| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v |
|---|---|

| | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
|---|---|
| Number of subjects included in analysis | 483 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference in Percentage |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.4 |
| upper limit | 5.2 |

**Primary: Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged >=2 to <5 Years to Those at 1 Month After Dose 2 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001 Study:Participants Without Evidence of Infection**

| End point title | Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged >=2 to <5 Years to Those at 1 Month After Dose 2 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001 Study:Participants Without Evidence of Infection |
|---|---|

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

| End point type | Primary |
|---|---|

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 2 and C4591001 control arm (16-25 years):1 month after Dose 2

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 143 | 170 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 1535.2 (1388.2 to 1697.8) | 1180.0 (1066.6 to 1305.4) | | |

### Statistical analyses

| **Statistical analysis title** | Geometric Mean Ratio |
|---|---|
| Statistical analysis description: | |
| Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers at 1 Month after dose 3 in Participants >=2 to <5 Years of age to those at 1 month after Dose 2 in participants 16 to 25 years of age from Phase 2/3 of the C4591001 study | |
| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
| Number of subjects included in analysis | 313 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Geometric Mean Ratio |
| Point estimate | 1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.13 |
| upper limit | 1.5 |

### Primary: Phase 2/3:Difference in Percentage of Participants With Seroresponse in 2 to <5 Years of Age Compared With Study C4591001 Phase 2/3 16 Through 25 Years of Age: Participants Without Evidence of Infection

| End point title | Phase 2/3:Difference in Percentage of Participants With Seroresponse in 2 to <5 Years of Age Compared With Study C4591001 Phase 2/3 16 Through 25 Years of Age: Participants Without Evidence of Infection |
|---|---|

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

| End point type | Primary |
|---|---|

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 3 and C4591001 control arm (16-25 years):1 month after Dose 2

| End point values | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 141 | 170 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 100.0 (97.4 to 100.0) | 98.8 (95.8 to 99.9) | | |

**Statistical analyses**

| Statistical analysis title | Difference in Percentages |
|---|---|

Statistical analysis description:

Phase 2/3: Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection – Immunobridging Subset – Comparison of Study C4591007 Phase 2/3 2 to <5 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2)

| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
|---|---|
| Number of subjects included in analysis | 311 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference in Percentages |
| Point estimate | 1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.5 |
| upper limit | 4.2 |

**Primary: Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged 6 Months to 2 Years to Those at 1 Month After Dose 3 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001:Participants Without Evidence of Infection**

| End point title | Phase 2/3:GMR for SARS-CoV-2 Neutralizing Titers at 1 Month After Dose 3 in Participants Aged 6 Months to 2 Years to Those at 1 Month After Dose 3 in Participants Aged 16 to 25 Years From Phase 2/3 of C4591001:Participants Without Evidence of Infection |
|---|---|

End point description:

GMRs and the corresponding 2-sided CIs were calculated by exponentiating the mean difference of the logarithm of the titers and the corresponding CIs(based on student t distribution).Assay results below the lower limit of quantitation(LLOQ))were set to 0.5*LLOQ.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants of the age 16 to 25 years who received 2 doses of original BNT162b2 30 mcg who had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 were also included.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.

N=participants evaluable.GMT is reported in descriptive analysis & GMR is reported under statistical analysis.

| End point type | Primary |
|---|---|

End point timeframe:

C4591007 (>=2 to <5 years):1 month after Dose 3 and C4591001 control arm (16-25 years):1 month after Dose 2

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 82 | 170 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 1406.5 (1211.3 to 1633.1) | 1180.0 (1066.6 to 1305.4) | | |

## Statistical analyses

| **Statistical analysis title** | Geometric Mean Ratio |
|---|---|

Statistical analysis description:

Phase 2/3: Geometric Mean Ratio for SARS-CoV-2 Neutralizing Titers at 1 Month after dose 3 in Participants 6 Months to <2 Years of age to those at 1 month after Dose 3 in participants 16 to 25 years of age from Phase 2/3 of the C4591001 study

| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
|---|---|
| Number of subjects included in analysis | 252 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Geometric mean ratio |
| Point estimate | 1.19 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1 |
| upper limit | 1.42 |

## Primary: Phase 2/3:Difference in Percentage of Participants With Seroresponse in 6 Months to <2 Years (1 Month After Dose 3) Compared With Study C4591001 Phase 2/3 16 Through 25 Years (1 Month After Dose 2): Participants Without Evidence of Infection

| End point title | Phase 2/3:Difference in Percentage of Participants With Seroresponse in 6 Months to <2 Years (1 Month After Dose 3) Compared With Study C4591001 Phase 2/3 16 Through 25 |
|---|---|

| | |
|---|---|
| | Years (1 Month After Dose 2): Participants Without Evidence of Infection |

End point description:

Seroresponse is defined as achieving a >=4-fold rise from baseline(before Dose 1). Assay result below a postvaccination >=4*LLOQ is considered a seroresponse.Results include those from a comparator group of C4591001(NCT04368728)Phase 2/3 participants who had no serological or virological evidence (prior to the 1-month post-Dose 2 blood sample collection) of past SARS-CoV-2 infection were included for this analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint. Percentage of participants with seroresponse is reported in descriptive analysis and the difference in percentage of participants is reported under statistical analysis.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

C4591007 (>=6 months to <2 years):1 month after Dose 3 and C4591001 control arm (16-25 years):1 month after Dose 2

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 80 | 170 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 100.0 (95.5 to 100.0) | 98.8 (95.8 to 99.9) | | |

## Statistical analyses

| **Statistical analysis title** | Difference in Percentages |
|---|---|

Statistical analysis description:

Phase 2/3: Difference in Percentages of Participants With Seroresponse – Participants Without Evidence of Infection – Immunobridging Subset – Comparison of Study C4591007 Phase 2/3 6 Months to <2 Years of Age (1 Month After Dose 3) and Study C4591001 Phase 2/3 16 Through 25 Years of Age (1 Month After Dose 2) – Evaluable Immunogenicity Population

| | |
|---|---|
| Comparison groups | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age v Historical cohort:C4591001 BNT162b2(30 mcg)16 Through 25 Years |
| Number of subjects included in analysis | 250 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference in percentage |
| Point estimate | 1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.4 |
| upper limit | 4.2 |

## Secondary: Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=2 to <5 Years of age: Participants Without Evidence of Infection

| End point title | Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=2 to <5 Years of age: Participants Without Evidence of Infection |
|---|---|

End point description:

GMT of SARS-CoV-2 neutralizing titers after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable Immunogenicity Population consisted of all eligible randomized participants who received 2 doses with the same dose level to which they were randomized, with Dose 2 received within the predefined window, had at least 1 valid and determinate immunogenicity result after Dose 2 from the blood sample collected within an appropriate window after Dose 2(within 6-8 days after Dose 2 for Phase 1), and had no other important protocol deviations as determined by the clinician.Participants without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Day 7 post Dose 2

| **End point values** | Phase 1: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 1: BNT162b2 (10 mcg): 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13 | 29 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 1350.4 (973.1 to 1873.9) | 2059.5 (1679.1 to 2526.0) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=6 Months to <2 Years of age: Participants Without Evidence of Infection

| End point title | Phase 1: Geometric Mean Titers (GMTs) of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=6 Months to <2 Years of age: Participants Without Evidence of Infection |
|---|---|

End point description:

GMT of SARS-CoV-2 neutralizing titers after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable Immunogenicity Population consisted of all eligible randomized participants who received 2 doses with the same dose level to which they were randomized, with Dose 2 received within the predefined window, had at least 1 valid and determinate immunogenicity result after Dose 2 from

the blood sample collected within an appropriate window after Dose 2(within 6-8 days after Dose 2 for Phase 1), and had no other important protocol deviations as determined by the clinician.Participants without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Day 7 post Dose 2

| **End point values** | Phase 1: BNT162b2 (3 mcg): 6 Months to < 2 years of age | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 13 | | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 1643.8 (1151.3 to 2347.1) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=5 to <12 Years of age: Participants Without Evidence of Infection

| End point title | Phase 1: GMTs of Severe Acute Respiratory Syndrome Coronavirus 2 Neutralizing Titers at 7 Days After Dose 2: >=5 to <12 Years of age: Participants Without Evidence of Infection |
|---|---|

End point description:

GMT of SARS-CoV-2 neutralizing titers after the study vaccination was reported in this endpoint. GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs(based on Student's t distribution).Assay results below the LLOQ were set to 0.5*LLOQ. Evaluable Immunogenicity Population consisted of all eligible randomized participants who received 2 doses with the same dose level to which they were randomized, with Dose 2 received within the predefined window, had at least 1 valid and determinate immunogenicity result after Dose 2 from the blood sample collected within an appropriate window after Dose 2(within 6-8 days after Dose 2 for Phase 1), and had no other important protocol deviations as determined by the clinician.Participants without evidence of prior infection were included in the analysis.'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Day 7 post Dose 2

| End point values | Phase 1: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 1: BNT162b2 (20 mcg): 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 15 | 15 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | 4162.6 (2584.7 to 6704.0) | 4583.4 (2802.9 to 7494.8) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age: Dose 1 to 1 Month After Dose 2:Participants Without Evidence of Infection

| End point title | Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age: Dose 1 to 1 Month After Dose 2:Participants Without Evidence of Infection |
|---|---|

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Pre-dose 1 and 1 month after Dose 2

| End point values | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 264 | 130 | | |
| Units: Titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Pre-dose 1 | 10.1 (9.9 to 10.3) | 10.0 (10.0 to 10.0) | | |
| 1 month after Dose 2 | 1197.6 (1106.1 to 1296.6) | 10.7 (9.7 to 11.8) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age:Dose 3 and 1 Month After Dose 3 :Participants Without Evidence of Infection

| End point title | Phase 2/3: Geometric Mean Titers – NT50: Immunogenicity Set – 5 to <12 Years of Age:Dose 3 and 1 Month After Dose 3 :Participants Without Evidence of Infection |
|---|---|

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Dose 3 set: Pre-dose 3 and 1 month after Dose 3

| **End point values** | Phase 2/3: BNT162b2 (10 mcg) 3-Dose Set | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 67 | | | |
| Units: Titers | | | | |
| number (confidence interval 95%) | | | | |
| Pre-dose 3 | 271.0 (229.1 to 320.6) | | | |
| 1 month after dose 3 | 2720.9 (2280.1 to 3247.0) | | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Geometric Mean Titers – NT50:2 to <5 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection

| End point title | Phase 2/3: Geometric Mean Titers – NT50:2 to <5 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection |
|---|---|

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5 *LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.

'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 143 | 59 | | |
| Units: Titers | | | | |
| number (confidence interval 95%) | | | | |
| Pre-dose 1 (n=141, 57) | 20.7 (20.3 to 21.2) | 20.5 (20.5 to 20.5) | | |
| Pre-dose 3 (n=143, 59) | 401.1 (361.7 to 444.7) | 20.9 (20.1 to 21.8) | | |
| 1 month after dose 3 (n=143, 59) | 1535.2 (1388.2 to 1697.8) | 22.9 (19.5 to 26.8) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Geometric Mean Titers- NT50:6 Months to <2 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection

| End point title | Phase 2/3: Geometric Mean Titers- NT50:6 Months to <2 Years of Age: Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3: Participants Without Evidence of Infection |
|---|---|

End point description:

GMTs and the corresponding 2-sided CIs were calculated by exponentiating the mean logarithm of the titers and the corresponding CIs (based on Student's t distribution). Assay results below the LLOQ were set to 0.5*LLOQ. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.
'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Pre-Dose 1, Pre-Dose 3 and 1 Month After Dose 3

| End point values | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 82 | 49 | | |
| Units: Titer | | | | |
| number (confidence interval 95%) | | | | |
| Pre- dose 1 (80, 48) | 20.8 (20.2 to 21.5) | 20.5 (20.5 to 20.5) | | |
| Pre-dose 3 (81, 49) | 317.0 (268.8 to 373.9) | 24.2 (19.7 to 29.8) | | |
| 1 Month After Dose 3 (82, 49) | 1406.5 (1211.3 to 1633.1) | 22.3 (18.8 to 26.4) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Neutralizing Titers From Dose 1 to 1 Month After Dose 2: >=5 to 12 Years of age: Participants Without Evidence of Infection

| End point title | Phase 2/3: Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Neutralizing Titers From Dose 1 to 1 Month After Dose 2: >=5 to 12 Years of age: Participants Without Evidence of Infection |
|---|---|

End point description:

GMFR of SARS-CoV-2 neutralizing titers from dose 1 to 1 month after dose 2 were reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Assay results below the LLOQ were set to 0.5* LLOQ in the analysis. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

From Dose 1 to 1 month after Dose 2

| End point values | Phase 2/3: BNT162b2 (10 mcg): 5 to <12 years of age | Phase 2/3: Placebo: 5 to <12 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 264 | 130 | | |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | 118.2 (109.2 to 127.9) | 1.1 (1.0 to 1.2) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=2 to 5 Years of age: Participants Without Evidence of Infection

| End point title | Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=2 to 5 Years of age: Participants Without Evidence of Infection |
|---|---|

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs(based on the Student t distribution). Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection and had no medical history of COVID-19 infection.Assay results below the LLOQ were set to 0.5*LLOQ in the analysis.Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised,had a valid and determinate immunogenicity result within 28-42 days after the study vaccination,and had no other important protocol deviations as determined by the clinician.'N'=participants evaluable in this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Pre-dose 3, 1 Month After Dose 3

| **End point values** | Phase 2/3: BNT162b2 (3 mcg): 2 to <5 years of age | Phase 2/3: Placebo: 2 to <5 years of age | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 141 | 57 | | |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Pre-dose 3 | 19.2 (17.4 to 21.3) | 1.0 (1.0 to 1.0) | | |
| 1 month after Dose 3 | 73.3 (66.3 to 81.1) | 1.1 (0.9 to 1.3) | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3:GMFR of SARS-CoV-2 Neutralizing Titers From Dose 3 to 1 Month After Dose 3: >=5 to 12 Years of age: Participants Without Evidence of Infection

| End point title | Phase 2/3:GMFR of SARS-CoV-2 Neutralizing Titers From Dose 3 to 1 Month After Dose 3: >=5 to 12 Years of age: Participants Without Evidence of Infection |
|---|---|

End point description:

GMFR of SARS-CoV-2 neutralizing titers from before Dose 3 to 1 month after Dose were reported in this endpoint. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection or had no medical history of COVID-19. Evaluable immunogenicity population included all eligible randomized participants who received the study interventions to which they were randomized, had a valid and determined immunogenicity result within 28-42 days after Dose 3, and had no other important protocol deviations as determined by the clinicians. 'N' = participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Before dose 1 to 1 month after dose 2, pre-dose 3 and 1 month after dose 3

| **End point values** | Phase 2/3: BNT162b2 (10 mcg) 3-Dose Set | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 67 | | | |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | 10.0 (8.1 to 12.4) | | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=6 Months to 2 Years of age: Participants Without Evidence of Infection

| End point title | Phase 2/3: GMFR of SARS-CoV-2 Neutralizing Titers From Before Dose 1 to Each Subsequent Time Point After Dose 3: >=6 Months to 2 Years of age: Participants Without Evidence of Infection |
|---|---|

End point description:

GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5*LLOQ in the analysis. Participants included in this analysis had no serological or virological evidence of past SARS-CoV-2 infection prior to the 1-month post–Dose 2. Evaluable immunogenicity population included all eligible randomised participants who received the study intervention to which they were randomised, had a valid and determinate immunogenicity result within 28-42 days after the study vaccination, and had no other important protocol deviations as determined by the clinician. 'N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

Pre-dose 3, 1 Month After Dose 3

| End point values | Phase 2/3: BNT162b2 (3 mcg): 6 months to <2 years of age | Phase 2/3: Placebo: 6 months to <2 years | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 80 | 48 | | |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Pre-dose 3 (79,48) | 15.4 (12.9 to 18.3) | 1.2 (1.0 to 1.5) | | |
| 1 month after Dose 3 (80,48) | 68.4 (58.2 to 80.4) | 1.1 (0.9 to 1.3) | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to Prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=5 to <12 Years of age

| End point title | Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to Prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=5 to <12 Years of age |
|---|---|

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 2 to prior to dose 3 without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.

| End point type | Secondary |
|---|---|

End point timeframe:

From 7 days after Dose 2 to prior to dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.591; Placebo - 0.292)

| End point values | Ph2/3:BNT162b2 3 mcg 5-<12Y:WoEI:evaluable efficacy(3-dose)set | Phase 2/3:Placebo 5 to <12Y:WoEI:evaluable efficacy(3- | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2703 | 1348 | | |
| Units: Cases | | | | |
| number (not applicable) | 10 | 42 | | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=6 Months to <5 Years of Age

| End point title | Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants Without Serological or Virological Evidence: >=6 Months to <5 Years of Age |
|---|---|

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 3 without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 3 received within the predefined window (within 19-42 days after Dose 2) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2. N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

From 7 Days After Dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.124; Placebo - 0.054)

| **End point values** | Ph2/3:BNT162b2 3mcg:6M-<5Y:WoEI:evaluable efficacy(3dose) set | Phase2/3:Placebo:6M-<5Y):WoEI:evaluable efficacy(3-dose)set | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 873 | 381 | | |
| Units: Cases | | | | |
| number (not applicable) | 13 | 21 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=5 to <12 Years of age

| End point title | Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 2 to prior to Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=5 to <12 Years of age |
|---|---|

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 2 to prior to dose 3 with or without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 2 received within the predefined window (within 19-42 days after Dose 1) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2.

| End point type | Secondary |
|---|---|

End point timeframe:

From 7 Days After Dose 2 to prior to dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.653; Placebo - 0.326)

| End point values | Phase 2/3:BNT162b2 3 mcg 5-<12Y:evaluable efficacy(3-dose)set | Phase 2/3:Placebo 5-<12Y:evaluable efficacy(3-dose)set | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 3108 | 1511 | | |
| Units: Cases | | | | |
| number (not applicable) | 12 | 42 | | |

### Statistical analyses

No statistical analyses for this end point

## Secondary: Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=6 Months to <5 Years of age

| End point title | Phase 2/3: Confirmed COVID-19 Cases From 7 Days After Dose 3 per 1000 Person-Years of Blinded Follow-up in Participants With or Without Serological or Virological Evidence: >=6 Months to <5 Years of age |
|---|---|

End point description:

Number of confirmed COVID-19 cases from 7 days after dose 3 without the evidence of infection were reported in this endpoint. Evaluable efficacy population included all eligible randomised subjects who received all vaccination(s) as randomized, with Dose 3 received within the predefined window (within 19-42 days after Dose 2) and have no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2. N'=participants evaluable for this endpoint.

| End point type | Secondary |
|---|---|

End point timeframe:

From 7 Days After Dose 3 (Surveillance time [1000 person-years]: BNT162b2 - 0.149; Placebo - 0.067)

| End point values | Phase 2/3:BNT162b2 3 mcg 6M<5Y:evaluable efficacy(3-dose)set | Phase 2/3:Placebo 6M-<5Y:evaluable efficacy(3- | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 1294 | 612 | | |
| Units: Cases | | | | |
| number (not applicable) | 14 | 23 | | |

### Statistical analyses

No statistical analyses for this end point

## Adverse events information

Timeframe for reporting adverse events:

Local/systemic events: Day 1 to 7 after each dose. Non SAE: Treatment emergent adverse events are reported from time of first dose of study treatment up to 1 month after last dose. SAE: From first dose to 6 months after last dose of study treatment

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE but are distinct events. An event may be categorised as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE.

| | |
|---|---|
| Assessment type | Non-systematic |

## Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 26.1 |

## Reporting groups

| | |
|---|---|
| Reporting group title | Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2or Prior D3/BNT162b2 3mcg |

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive dose 1 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period were followed up to 6 month after dose 2 or prior to dose 3.

| | |
|---|---|
| Reporting group title | Ph2/3:Bl PCFup:6 M -<2Y:D1-1M After D2/BNT162b2 3 mcg |

Reporting group description:

Phase 2/3 (Ph2/3): Participants aged 6 months to <2 years (6 M -<2 Yrs) were randomised to receive dose 1 (D1) of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period (Bl PCFup) and were followed up to 1 month after dose 2 (1M After D2).

| | |
|---|---|
| Reporting group title | Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/Pb |

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo)(Pb) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

| | |
|---|---|
| Reporting group title | Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/Pb |

Reporting group description:

Phase 2/3:Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

| | |
|---|---|
| Reporting group title | Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/BNT162b2 3mcg |

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

| | |
|---|---|
| Reporting group title | Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/Pb |

Reporting group description:

Phase 2/3:Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

| | |
|---|---|
| Reporting group title | Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/BNT162b2 3mcg |

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

| | |
|---|---|
| Reporting group title | Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2 or Prior D3/Pb |

Reporting group description:

Phase 2/3: Participants aged 6 months to <2 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were

followed up to 6 month after dose 2 or prior to dose 3.

| Reporting group title | Ph2/3:Bl PCFup:5-<12Y:D1-1M After D2/ BNT162b2 10mcg |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 5 to <12 years were randomised to receive dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

| Reporting group title | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period in Troponin group and were followed up to 6 month after dose 2.

| Reporting group title | Ph2/3:BlPCFup:5-<12Y:TPG:D1-6MAfterD2 orPriorD3/BNT162b210mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period in Troponin group (TPG) and were followed up to 6 month after dose 2 or prior to dose 3.

| Reporting group title | Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/Pb |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

| Reporting group title | Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/BNT162b2 3mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 2 to <5 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 3.

| Reporting group title | Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/Pb |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/BNT162b2 3mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 2 to <5 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/Pb |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 2 or Prior to Dose 3.

| Reporting group title | Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/BNT162b2 3mcg |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive dose 1 of BNT162b2 3 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 6 month after dose 2 or Prior to Dose 3.

| Reporting group title | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2 or Prior D3/Pb |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period in Troponin group and were followed up to 6 month after dose 2 or prior to dose 3.

| Reporting group title | Ph2/3:BlPCFup:2-<5Y:D1-1M After D2/ BNT162b2 3mcg |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive dose 3 of BNT162b2 3 mcg intramuscularly in blinded placebo-controlled follow up period and were followed up from dose 1 to 1 month after dose 2.

| Reporting group title | Ph2/3:Bl PCFup:2-<5Y:D1-1M After D2/Pb |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 2 to <5 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in blinded placebo controlled follow up period and were followed from Dose 1 to 1 month after dose 2.

| Reporting group title | Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 5 to <12 years were randomised to receive dose 3 of BNT162b2 10 mcg intramuscularly in Blinded and Open Label Period (OLP) in Troponin group and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:Bl OLP:5-<12Y:TPG:D3-6M After D3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 6 month after dose 3.

| Reporting group title | Ph1:2-<5Y:D1-1M After D2/BNT162b2 3 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 2 to <5 years received dose 1 of BNT162b2 3 mcg intramuscularly and were followed up to 1 month after dose 2.

| Reporting group title | Ph1:6M-<2Y:D3-1M After D3/BNT162b2 3 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 6 months to <2 years received dose 3 of BNT162b2 3 mcg intramuscularly and were followed up to 1 month after dose 3.

| Reporting group title | Ph1:6M-<2Y:D1-6M After D2/BNT162b2 3 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 6 months to <2 years received dose 1 of BNT162b2 3 mcg intramuscularly and were followed up to 6 month after dose 2.

| Reporting group title | Ph2/3:OLP:12-<16Y:TPG:D3-1M After D3/BNT162b2 30 mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 12 to <16 years were randomised to receive dose 3 of BNT162b2 30 mcg intramuscularly in open label in Troponin group and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:OLP:12-<16Y:TPG:D1-6M After D2or priorD3/BNT162b2 30mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 12 to <16 years were randomised to receive dose 1 of BNT162b2 30 mcg intramuscularly in open label in Troponin group and were followed up to 6 month after dose 2 or prior to dose 3.

| Reporting group title | Ph2/3:OLP:12-<16Y:TPG:D1-1M After D2/BNT162b2 30 mcg |
|---|---|

Reporting group description:

Phase 2/3: Participants aged 12 to <16 years were randomised to receive dose 1 of BNT162b2 30 mcg intramuscularly in Open label in Troponin group and were followed up to 1 month after dose 2.

| Reporting group title | Ph1:2-<5Y:D1-1M After D2/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 2 to <5 years received dose 1 of BNT162b2 10 mcg intramuscularly and were followed up to 1 month after dose 2.

| Reporting group title | Ph1:2-<5Y:D3-1M After D3/BNT162b2 3 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 2 to <5 years received dose 3 of BNT162b2 3 mcg intramuscularly and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/Pb |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 5 to <12 years received 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2 or prior to dose 3.

| Reporting group title | Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive dose 3 as BNT162b2 10 mcg in Blinded and Open Label Period and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 1 month after dose 3.

| Reporting group title | Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 5 to <12 years received dose 1 of BNT162b2 10 mcg intramuscularly and were followed up to 6 month after dose 2.

| Reporting group title | Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 5 to <12 years received dose 1 of BNT162b2 10 mcg intramuscularly and were followed up to 6 month after dose 2.

| Reporting group title | Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/30 mcg) |
|---|---|

Reporting group description:

Phase 1: Participants aged 5 to <12 years of age received dose 1 of 30 mcg BNT162b2 and received third dose of 10 mcg BNT162b2 were followed up to 1 month after dose 2.

| Reporting group title | Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/10 mcg) |
|---|---|

Reporting group description:

Phase 1: Participants aged 5 to <12 years of age received dose 1 of 30 mcg, followed by dose 2 of 10 mcg BNT162b2 and received third dose of 10 mcg BNT162b2 were followed up to 1 month after dose 2.

| Reporting group title | Ph1:5-<12Y:D3-1M After D3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 1: Participants aged 5 to <12 years received dose 3 of BNT162b2 10 mcg intramuscularly and were followed up to 1 month after dose 3.

| Reporting group title | Ph2/3:Bl PCFup:6M-<2Y:D1-1M After D2/Placebo |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 6 months to <2 years were received 0.9% sodium chloride solution for Injection intramuscularly (Placebo) in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

| Reporting group title | Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Phase 2/3:Participants aged 5 to <12 years received dose 1 of BNT162b2 10 mcg intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2 or prior to dose 3.

| Reporting group title | Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/Org BNT162b2 10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years received dose 3 as Original (Org) BNT162b2 10 mcg in Blinded and Open Label Period were followed up to 6 month after dose 3.

| Reporting group title | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-1M After D2/Pb BNT162b2 10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded Placebo-Controlled Follow-Up Period and were followed up to 1 month after dose 2.

| Reporting group title | Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/BNT162b2 10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive dose 3 as BNT162b2 10 mcg in Blinded

and Open Label Period and were followed up to 6 month after dose 3.

| Reporting group title | Ph2/3:Bl OLP:5-<12Y:TPG:D3-1M After D3/Org BNT162b2 10 mcg |
|---|---|

Reporting group description:

Participants aged 5 to <12 years were randomised to receive 0.9% sodium chloride solution for Injection intramuscularly (Placebo) intramuscularly in Blinded and Open Label period and had the opportunity to receive dose 3 as BNT162b2 10 mcg in Open Label Period in Troponin group and were followed up to 6 month after dose 3.

| **Serious adverse events** | Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2or Prior D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/BNT162b2 3 mcg | Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/Pb |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 24 / 1458 (1.65%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |

| | | | |
|---|---|---|---|
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 3 / 1458 (0.21%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 3 / 1458 (0.21%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 1458 (0.14%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 2 / 1458 (0.14%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 5 / 1458 (0.34%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 1 / 1458 (0.07%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/Pb | Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/Pb |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 1 / 483 (0.21%) | 0 / 237 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Vomiting | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 1 / 483 (0.21%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/BNT162b2 3mcg | Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2 or Prior D3/Pb | Ph2/3:Bl PCFup:5-<12Y:D1-1M After D2/ BNT162b2 10mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 17 / 718 (2.37%) | 0 / 3109 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 2 / 718 (0.28%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Constipation | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 3 / 718 (0.42%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 1 / 718 (0.14%) | 0 / 3109 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2/BNT162b2 10 mcg | Ph2/3:BlPCFup:5-<12Y:TPG:D1-6MAfterD2 orPriorD3/BNT162b2 10mcg | Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/Pb |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 1 / 518 (0.19%) | 0 / 405 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 1 / 518 (0.19%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Fall | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/Pb | Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/BNT162b2 3mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 863 (0.35%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 1 / 863 (0.12%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Vomiting | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 1 / 863 (0.12%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 863 (0.12%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/Pb | Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2 or Prior D3/Pb |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 10 / 1173 (0.85%) | 11 / 2368 (0.46%) | 0 / 260 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Constipation | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 2 / 2368 (0.08%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 1 / 1173 (0.09%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 1 / 2368 (0.04%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 2 / 2368 (0.08%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:BlPCFup:2-<5Y:D1-1M After D2/ BNT162b2 3mcg | Ph2/3:Bl PCFup:2-<5Y:D1-1M After D2/Pb | Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:TPG:D3-6M After D3/BNT162b2 10 mcg | Ph1:2-<5Y:D1-1M After D2/BNT162b2 3 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 2 / 418 (0.48%) | 0 / 16 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |

| | | | |
|---|---|---|---|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 1 / 418 (0.24%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 1 / 418 (0.24%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Vomiting | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph1:6M-<2Y:D3-1M After D3/BNT162b2 3 mcg | Ph1:6M-<2Y:D1-6M After D2/BNT162b2 3 mcg | Ph2/3:OLP:12-<16Y:TPG:D3-1M After D3/BNT162b2 30 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Constipation | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:OLP:12-<16Y:TPG:D1-6M After D2or priorD3/BNT162b2 30mcg | Ph2/3:OLP:12-<16Y:TPG:D1-1M After D2/BNT162b2 30 mcg | Ph1:2-<5Y:D1-1M After D2/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 487 (0.41%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 487 (0.21%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 1 / 487 (0.21%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Fall | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph1:2-<5Y:D3-1M After D3/BNT162b2 3 mcg | Ph2/3:BlPCFup:5 - <12Y:D1-1M After D2 or PTD3/Pb | Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 3 / 1538 (0.20%) | 0 / 2410 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |

| | | | |
|---|---|---|---|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 1 / 1538 (0.07%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 1 / 1538 (0.07%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 1 / 1538 (0.07%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Vomiting | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 1 / 1538 (0.07%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg | Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg | Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Constipation | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/30 mcg) | Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/10 mcg) | Ph1:5-<12Y:D3-1M After D3/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |

| | | | |
|---|---|---|---|
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue | | | |

| | | | |
|---|---|---|---|
| disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:Bl PCFup:6M-<2Y:D1-1M After D2/Placebo | Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/Org BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 8 / 3109 (0.26%) | 3 / 957 (0.31%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |

| | | | |
|---|---|---|---|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 1 / 957 (0.10%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 1 / 957 (0.10%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Vomiting | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 1 / 957 (0.10%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 1 / 957 (0.10%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 1 / 3109 (0.03%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-1M After D2/Pb BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:TPG:D3-1M After D3/Org BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 10 / 2410 (0.41%) | 0 / 202 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Cyanosis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Ovarian cyst | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Testicular appendage torsion | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute respiratory failure | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumomediastinum | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory arrest | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory distress | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Disruptive mood dysregulation disorder | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Accidental overdose | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Burns second degree | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Epiphyseal fracture | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eyelid injury | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Femur fracture | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body ingestion | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Head injury | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Thermal burn | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper limb fracture | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Epilepsy | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile convulsion | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Narcolepsy | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Seizure | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Status epilepticus | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Syncope | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Papilloedema | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Constipation | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Intestinal obstruction | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pancreatitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermal cyst | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Abdominal abscess | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Acute sinusitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Anal abscess | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Appendicitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 1 / 2410 (0.04%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthritis bacterial | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Complicated appendicitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterovirus infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Exanthema subitum | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Focal peritonitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis adenovirus | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis norovirus | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis rotavirus | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| HCoV-NL63 infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Large intestine infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lower respiratory tract infection viral | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metapneumovirus infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Parainfluenzae virus infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia respiratory syncytial viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus bronchiolitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory syncytial virus infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Feeding intolerance | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoglycaemia | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 1 %

| **Non-serious adverse events** | Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2or Prior D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/BNT162b2 3 mcg | Ph2/3:Bl PCFup:6 M-<2Y:D1-1M After D2/Pb |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 1154 / 1458 (79.15%) | 550 / 718 (76.60%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 237 / 1458 (16.26%) | 83 / 718 (11.56%) |
| occurrences (all) | 0 | 285 | 96 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 353 / 1458 (24.21%) | 126 / 718 (17.55%) |
| occurrences (all) | 0 | 448 | 151 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 94 / 1458 (6.45%) | 26 / 718 (3.62%) |
| occurrences (all) | 0 | 108 | 28 |
| Malaise | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 43 / 1458 (2.95%) | 14 / 718 (1.95%) |
| occurrences (all) | 0 | 45 | 14 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 184 / 1458 (12.62%) | 87 / 718 (12.12%) |
| occurrences (all) | 0 | 205 | 96 |

| | | | |
|---|---|---|---|
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 15 / 1458 (1.03%) | 5 / 718 (0.70%) |
| occurrences (all) | 0 | 18 | 5 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 20 / 1458 (1.37%) | 5 / 718 (0.70%) |
| occurrences (all) | 0 | 21 | 5 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 15 / 1458 (1.03%) | 6 / 718 (0.84%) |
| occurrences (all) | 0 | 16 | 7 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 932 / 1458 (63.92%) | 431 / 718 (60.03%) |
| occurrences (all) | 0 | 1343 | 615 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 560 / 1458 (38.41%) | 274 / 718 (38.16%) |
| occurrences (all) | 0 | 713 | 354 |

| | | | |
|---|---|---|---|
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 31 / 1458 (2.13%) | 17 / 718 (2.37%) |
| occurrences (all) | 0 | 31 | 17 |
| Nausea | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 18 / 1458 (1.23%) | 7 / 718 (0.97%) |
| occurrences (all) | 0 | 18 | 7 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 27 / 1458 (1.85%) | 15 / 718 (2.09%) |
| occurrences (all) | 0 | 29 | 17 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---|---|---|
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 10 / 1458 (0.69%) | 8 / 718 (1.11%) |
| occurrences (all) | 0 | 10 | 8 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 16 / 1458 (1.10%) | 11 / 718 (1.53%) |
| occurrences (all) | 0 | 16 | 11 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 0 / 1458 (0.00%) | 0 / 718 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1458 (0.00%) | 511 / 1458 (35.05%) | 236 / 718 (32.87%) |
| occurrences (all) | 0 | 619 | 279 |

| Non-serious adverse events | Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/Pb | Ph2/3:Bl PCFup:6M-<2Y:D3-6M After D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/Pb |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 119 / 237 (50.21%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 11 / 237 (4.64%) |
| occurrences (all) | 0 | 0 | 11 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Injection site pain (PAIN)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (TENDERNESS)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 22 / 237 (9.28%) |
| occurrences (all) | 0 | 0 | 22 |
| Injection site swelling (SWELLING)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 5 / 237 (2.11%) |
| occurrences (all) | 0 | 0 | 5 |
| Malaise | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 2 / 237 (0.84%) |
| occurrences (all) | 0 | 0 | 2 |
| Pyrexia (FEVER)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 13 / 237 (5.49%) |
| occurrences (all) | 0 | 0 | 13 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|---|---|---|---|
| Cough | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 82 / 237 (34.60%) |
| occurrences (all) | 0 | 0 | 82 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Fracture | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 27 / 237 (11.39%) |
| occurrences (all) | 0 | 0 | 27 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: | | | |

| | | | |
|---|---|---|---|
| Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 7 / 237 (2.95%) |
| occurrences (all) | 0 | 0 | 7 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 4 / 237 (1.69%) |
| occurrences (all) | 0 | 0 | 4 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 0 / 237 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 237 (0.00%) | 0 / 483 (0.00%) | 29 / 237 (12.24%) |
| occurrences (all) | 0 | 0 | 29 |

| **Non-serious adverse events** | Ph2/3:Bl PCFup:6M-<2Y:D3-1M After D3/BNT162b2 3mcg | Ph2/3:BlPCFup:6M-<2Y:D1-6M After D2 or Prior D3/Pb | Ph2/3:Bl PCFup:5-<12Y:D1-1M After D2/ BNT162b2 10mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 267 / 483 (55.28%) | 0 / 718 (0.00%) | 2821 / 3109 (90.74%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 413 / 3109 (13.28%) |
| occurrences (all) | 0 | 0 | 475 |
| Fatigue | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 1614 / 3109 (51.91%) |
| occurrences (all) | 0 | 0 | 2267 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 33 / 483 (6.83%) | 0 / 718 (0.00%) | 806 / 3109 (25.92%) |
| occurrences (all) | 33 | 0 | 1009 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 2603 / 3109 (83.72%) |
| occurrences (all) | 0 | 0 | 4439 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 67 / 483 (13.87%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 67 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 15 / 483 (3.11%) | 0 / 718 (0.00%) | 622 / 3109 (20.01%) |
| occurrences (all) | 15 | 0 | 770 |

| | | | |
|---|---|---|---|
| Malaise | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 12 / 483 (2.48%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 13 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 28 / 483 (5.80%) | 0 / 718 (0.00%) | 243 / 3109 (7.82%) |
| occurrences (all) | 28 | 0 | 257 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 191 / 483 (39.54%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 191 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 1193 / 3109 (38.37%) |
| occurrences (all) | 0 | 0 | 1573 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 98 / 483 (20.29%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 98 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 320 / 3109 (10.29%) |
| occurrences (all) | 0 | 0 | 364 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 6 / 483 (1.24%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 122 / 3109 (3.92%) |
| occurrences (all) | 0 | 0 | 125 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 235 / 3109 (7.56%) |
| occurrences (all) | 0 | 0 | 265 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 561 / 3109 (18.04%) |
| occurrences (all) | 0 | 0 | 657 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 4 / 483 (0.83%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 483 (0.00%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 89 / 483 (18.43%) | 0 / 718 (0.00%) | 0 / 3109 (0.00%) |
| occurrences (all) | 89 | 0 | 0 |

| **Non-serious adverse events** | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2/BNT162b2 10 mcg | Ph2/3:BlPCFup:5-<12Y:TPG:D1-6MAfterD2 orPriorD3/BNT162b2 10mcg | Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/Pb |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 442 / 518 (85.33%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 50 / 518 (9.65%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 54 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 221 / 518 (42.66%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 256 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 92 / 518 (17.76%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 107 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 397 / 518 (76.64%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 522 | 0 | 0 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 69 / 518 (13.32%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 77 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 16 / 518 (3.09%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 16 | 0 | 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Concussion | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 163 / 518 (31.47%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 185 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 40 / 518 (7.72%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 46 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 13 / 518 (2.51%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 14 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 35 / 518 (6.76%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 39 | 0 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 81 / 518 (15.64%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 92 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 4 / 518 (0.77%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 518 (0.00%) | 0 / 518 (0.00%) | 0 / 405 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph2/3:Bl PCFup:2-<5Y:D3-6M After D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/Pb | Ph2/3:Bl PCFup:2-<5Y:D3-1M After D3/BNT162b2 3mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 152 / 405 (37.53%) | 398 / 863 (46.12%) |
| General disorders and administration site conditions | | | |

| | | | |
|---|---|---|---|
| Axillary pain | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 10 / 405 (2.47%) | 22 / 863 (2.55%) |
| occurrences (all) | 0 | 10 | 22 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 91 / 405 (22.47%) | 202 / 863 (23.41%) |
| occurrences (all) | 0 | 91 | 202 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 18 / 405 (4.44%) | 83 / 863 (9.62%) |
| occurrences (all) | 0 | 18 | 83 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 48 / 405 (11.85%) | 222 / 863 (25.72%) |
| occurrences (all) | 0 | 48 | 222 |
| Injection site pain (TENDERNESS) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 6 / 405 (1.48%) | 25 / 863 (2.90%) |
| occurrences (all) | 0 | 6 | 25 |
| Malaise | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 6 / 405 (1.48%) | 11 / 863 (1.27%) |
| occurrences (all) | 0 | 6 | 11 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 21 / 405 (5.19%) | 41 / 863 (4.75%) |
| occurrences (all) | 0 | 21 | 41 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 15 / 405 (3.70%) | 36 / 863 (4.17%) |
| occurrences (all) | 0 | 15 | 36 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 21 / 405 (5.19%) | 39 / 863 (4.52%) |
| occurrences (all) | 0 | 21 | 39 |
| Diarrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 863 (0.00%) | 5 / 405 (1.23%) | 1 / 863 (0.12%) |
| occurrences (all) | 0 | 5 | 1 |
| Nausea | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 7 / 405 (1.73%) | 2 / 863 (0.23%) |
| occurrences (all) | 0 | 7 | 2 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 16 / 405 (3.95%) | 16 / 863 (1.85%) |
| occurrences (all) | 0 | 16 | 16 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|---|---|---|
| Arthralgia | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 4 / 405 (0.99%) | 9 / 863 (1.04%) |
| occurrences (all) | 0 | 4 | 9 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 6 / 405 (1.48%) | 15 / 863 (1.74%) |
| occurrences (all) | 0 | 6 | 15 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 863 (0.00%) | 0 / 405 (0.00%) | 0 / 863 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/Pb | Ph2/3:BlPCFup:2-<5Y:D1-6M After D2 or Prior D3/BNT162b2 3mcg | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-6M After D2 or Prior D3/Pb |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site bruising | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---|---|---|
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1173 (0.00%) | 0 / 2368 (0.00%) | 0 / 260 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | Ph2/3:BlPCFup:2-<5Y:D1-1M After D2/ BNT162b2 3mcg | Ph2/3:Bl PCFup:2-<5Y:D1-1M After D2/Pb | Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1661 / 2368 (70.14%) | 778 / 1173 (66.33%) | 22 / 202 (10.89%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 125 / 2368 (5.28%) | 59 / 1173 (5.03%) | 0 / 202 (0.00%) |
| occurrences (all) | 129 | 63 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 3 / 202 (1.49%) |
| occurrences (all) | 0 | 0 | 3 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 977 / 2368 (41.26%) | 487 / 1173 (41.52%) | 0 / 202 (0.00%) |
| occurrences (all) | 1247 | 622 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 379 / 2368 (16.01%) | 136 / 1173 (11.59%) | 0 / 202 (0.00%) |
| occurrences (all) | 444 | 154 | 0 |
| Injection site pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 17 / 202 (8.42%) |
| occurrences (all) | 0 | 0 | 18 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 998 / 2368 (42.15%) | 357 / 1173 (30.43%) | 0 / 202 (0.00%) |
| occurrences (all) | 1329 | 449 | 0 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 182 / 2368 (7.69%) | 53 / 1173 (4.52%) | 0 / 202 (0.00%) |
| occurrences (all) | 209 | 57 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 37 / 2368 (1.56%) | 23 / 1173 (1.96%) | 4 / 202 (1.98%) |
| occurrences (all) | 37 | 24 | 4 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 224 / 2368 (9.46%) | 121 / 1173 (10.32%) | 0 / 202 (0.00%) |
| occurrences (all) | 237 | 126 | 0 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |

| | | | |
|---|---|---|---|
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 22 / 2368 (0.93%) | 14 / 1173 (1.19%) | 0 / 202 (0.00%) |
| occurrences (all) | 22 | 14 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 191 / 2368 (8.07%) | 86 / 1173 (7.33%) | 0 / 202 (0.00%) |
| occurrences (all) | 211 | 99 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 305 / 2368 (12.88%) | 160 / 1173 (13.64%) | 0 / 202 (0.00%) |
| occurrences (all) | 338 | 179 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 22 / 2368 (0.93%) | 13 / 1173 (1.11%) | 0 / 202 (0.00%) |
| occurrences (all) | 24 | 13 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 41 / 2368 (1.73%) | 13 / 1173 (1.11%) | 0 / 202 (0.00%) |
| occurrences (all) | 42 | 13 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 144 / 2368 (6.08%) | 68 / 1173 (5.80%) | 0 / 202 (0.00%) |
| occurrences (all) | 150 | 69 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Rash | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 53 / 2368 (2.24%) | 30 / 1173 (2.56%) | 0 / 202 (0.00%) |
| occurrences (all) | 53 | 33 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 106 / 2368 (4.48%) | 50 / 1173 (4.26%) | 0 / 202 (0.00%) |
| occurrences (all) | 114 | 54 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 2 / 202 (0.99%) |
| occurrences (all) | 0 | 0 | 2 |
| Ear infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 14 / 2368 (0.59%) | 12 / 1173 (1.02%) | 0 / 202 (0.00%) |
| occurrences (all) | 14 | 12 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 2368 (0.00%) | 0 / 1173 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph2/3:5-<12Y:TPG:D3-1M After D3/BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:TPG:D3-6M After D3/BNT162b2 10 mcg | Ph1:2-<5Y:D1-1M After D2/BNT162b2 3 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 319 / 418 (76.32%) | 0 / 418 (0.00%) | 10 / 16 (62.50%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 5 / 418 (1.20%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: | | | |

| | | | |
|---|---|---|---|
| Systematic | | | |
| subjects affected / exposed | 35 / 418 (8.37%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 35 | 0 | 2 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 153 / 418 (36.60%) | 0 / 418 (0.00%) | 5 / 16 (31.25%) |
| occurrences (all) | 153 | 0 | 8 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 67 / 418 (16.03%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 67 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 7 / 418 (1.67%) | 0 / 418 (0.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 7 | 0 | 2 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 273 / 418 (65.31%) | 0 / 418 (0.00%) | 7 / 16 (43.75%) |
| occurrences (all) | 273 | 0 | 11 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 50 / 418 (11.96%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 50 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 418 (0.48%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 18 / 418 (4.31%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 18 | 0 | 1 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Irritability | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Concussion | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Headache (HEADACHE)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 93 / 418 (22.25%) | 0 / 418 (0.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 93 | 0 | 4 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 19 / 418 (4.55%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 19 | 0 | 2 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 7 / 418 (1.67%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 7 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 23 / 418 (5.50%) | 0 / 418 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 23 | 0 | 1 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 73 / 418 (17.46%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 73 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 8 / 418 (1.91%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 418 (0.00%) | 0 / 418 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph1:6M-<2Y:D3-1M After D3/BNT162b2 3 mcg | Ph1:6M-<2Y:D1-6M After D2/BNT162b2 3 mcg | Ph2/3:OLP:12-<16Y:TPG:D3-1M After D3/BNT162b2 30 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 15 (46.67%) | 10 / 16 (62.50%) | 285 / 433 (65.82%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 52 / 433 (12.01%) |
| occurrences (all) | 0 | 0 | 52 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 149 / 433 (34.41%) |
| occurrences (all) | 0 | 0 | 149 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 15 (13.33%) | 3 / 16 (18.75%) | 14 / 433 (3.23%) |
| occurrences (all) | 2 | 3 | 14 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 257 / 433 (59.35%) |
| occurrences (all) | 0 | 0 | 257 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 15 (26.67%) | 1 / 16 (6.25%) | 0 / 433 (0.00%) |
| occurrences (all) | 4 | 1 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 1 / 16 (6.25%) | 12 / 433 (2.77%) |
| occurrences (all) | 1 | 1 | 12 |
| Malaise | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 2 / 16 (12.50%) | 14 / 433 (3.23%) |
| occurrences (all) | 1 | 3 | 14 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 16 (6.25%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 15 (26.67%) | 8 / 16 (50.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 4 | 12 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Concussion | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 143 / 433 (33.03%) |
| occurrences (all) | 0 | 0 | 143 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 4 / 16 (25.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 1 | 5 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 1 / 15 (6.67%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|---|---|---|
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 18 / 433 (4.16%) |
| occurrences (all) | 0 | 0 | 18 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 11 / 433 (2.54%) |
| occurrences (all) | 0 | 0 | 11 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 1 / 16 (6.25%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 26 / 433 (6.00%) |
| occurrences (all) | 0 | 0 | 26 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 76 / 433 (17.55%) |
| occurrences (all) | 0 | 0 | 76 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 15 (0.00%) | 0 / 16 (0.00%) | 0 / 433 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 15 (13.33%) | 2 / 16 (12.50%) | 0 / 433 (0.00%) |
| occurrences (all) | 2 | 3 | 0 |

| **Non-serious adverse events** | Ph2/3:OLP:12-<16Y:TPG:D1-6M After D2or priorD3/BNT162b2 30mcg | Ph2/3:OLP:12-<16Y:TPG:D1-1M After D2/BNT162b2 30 mcg | Ph1:2-<5Y:D1-1M After D2/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 414 / 487 (85.01%) | 32 / 32 (100.00%) |

| | | | |
|---|---|---|---|
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 88 / 487 (18.07%) | 3 / 32 (9.38%) |
| occurrences (all) | 0 | 104 | 4 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 255 / 487 (52.36%) | 23 / 32 (71.88%) |
| occurrences (all) | 0 | 364 | 34 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 12 / 487 (2.46%) | 9 / 32 (28.13%) |
| occurrences (all) | 0 | 14 | 14 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 3 / 32 (9.38%) |
| occurrences (all) | 0 | 0 | 3 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 384 / 487 (78.85%) | 21 / 32 (65.63%) |
| occurrences (all) | 0 | 603 | 37 |

| | | | |
|---|---|---|---|
| Injection site pain (TENDERNESS)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 27 / 487 (5.54%) | 4 / 32 (12.50%) |
| occurrences (all) | 0 | 29 | 4 |
| Malaise | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia (FEVER)<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 33 / 487 (6.78%) | 9 / 32 (28.13%) |
| occurrences (all) | 0 | 35 | 12 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Fall | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Fracture | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 228 / 487 (46.82%) | 8 / 32 (25.00%) |
| occurrences (all) | 0 | 307 | 8 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 0 | 2 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 66 / 487 (13.55%) | 5 / 32 (15.63%) |
| occurrences (all) | 0 | 75 | 6 |
| Diarrhoea | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 22 / 487 (4.52%) | 2 / 32 (6.25%) |
| occurrences (all) | 0 | 24 | 3 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Erythema | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|---|---|---|
| Arthralgia | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 69 / 487 (14.17%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 80 | 1 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 1 / 32 (3.13%) |
| occurrences (all) | 0 | 0 | 2 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 167 / 487 (34.29%) | 4 / 32 (12.50%) |
| occurrences (all) | 0 | 213 | 5 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 6 / 487 (1.23%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 6 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 487 (0.00%) | 0 / 487 (0.00%) | 0 / 32 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph1:2-<5Y:D3-1M After D3/BNT162b2 3 mcg | Ph2/3:BlPCFup:5 - <12Y:D1-1M After D2 or PTD3/Pb | Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 17 / 27 (62.96%) | 0 / 1538 (0.00%) | 1794 / 2410 (74.44%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 231 / 2410 (9.59%) |
| occurrences (all) | 0 | 0 | 231 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 14 / 2410 (0.58%) |
| occurrences (all) | 0 | 0 | 14 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 8 / 27 (29.63%) | 0 / 1538 (0.00%) | 897 / 2410 (37.22%) |
| occurrences (all) | 8 | 0 | 897 |
| Injection site bruising | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 27 (3.70%) | 0 / 1538 (0.00%) | 354 / 2410 (14.69%) |
| occurrences (all) | 1 | 0 | 354 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 34 / 2410 (1.41%) |
| occurrences (all) | 0 | 0 | 34 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 9 / 27 (33.33%) | 0 / 1538 (0.00%) | 1568 / 2410 (65.06%) |
| occurrences (all) | 9 | 0 | 1568 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 286 / 2410 (11.87%) |
| occurrences (all) | 0 | 0 | 286 |
| Malaise | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 13 / 2410 (0.54%) |
| occurrences (all) | 0 | 0 | 13 |
| Pyrexia (FEVER) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 154 / 2410 (6.39%) |
| occurrences (all) | 0 | 0 | 154 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|---|---|---|
| Animal bite | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 27 (3.70%) | 0 / 1538 (0.00%) | 610 / 2410 (25.31%) |
| occurrences (all) | 1 | 0 | 610 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 40 / 2410 (1.66%) |
| occurrences (all) | 0 | 0 | 40 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 27 (3.70%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 27 (3.70%) | 0 / 1538 (0.00%) | 104 / 2410 (4.32%) |
| occurrences (all) | 1 | 0 | 104 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 27 (3.70%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 2 / 27 (7.41%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 61 / 2410 (2.53%) |
| occurrences (all) | 0 | 0 | 61 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 129 / 2410 (5.35%) |
| occurrences (all) | 0 | 0 | 129 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 350 / 2410 (14.52%) |
| occurrences (all) | 0 | 0 | 350 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 1 / 27 (3.70%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 27 (0.00%) | 0 / 1538 (0.00%) | 0 / 2410 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph2/3:BlOLP:5-<12Y:D3-1M After D3/BNT162b2 10 mcg | Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg | Ph1:5-<12Y:D1-6M After D2/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 80 / 957 (8.36%) | 16 / 16 (100.00%) | 16 / 16 (100.00%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 5 / 16 (31.25%) | 7 / 16 (43.75%) |
| occurrences (all) | 0 | 5 | 11 |
| Fatigue | | | |
| subjects affected / exposed | 16 / 957 (1.67%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 16 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 14 / 16 (87.50%) | 13 / 16 (81.25%) |
| occurrences (all) | 0 | 19 | 21 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 8 / 16 (50.00%) | 3 / 16 (18.75%) |
| occurrences (all) | 0 | 8 | 3 |

| | | | |
|---|---|---|---|
| Injection site pain | | | |
| subjects affected / exposed | 60 / 957 (6.27%) | 1 / 16 (6.25%) | 1 / 16 (6.25%) |
| occurrences (all) | 60 | 1 | 1 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 14 / 16 (87.50%) | 15 / 16 (93.75%) |
| occurrences (all) | 0 | 28 | 27 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 8 / 16 (50.00%) | 3 / 16 (18.75%) |
| occurrences (all) | 0 | 8 | 4 |
| Malaise | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 10 / 957 (1.04%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 10 | 0 | 1 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 3 / 16 (18.75%) | 4 / 16 (25.00%) |
| occurrences (all) | 0 | 3 | 4 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Reproductive system and breast disorders | | | |

| | | | |
|---|---|---|---|
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Irritability | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 10 / 16 (62.50%) | 11 / 16 (68.75%) |
| occurrences (all) | 0 | 12 | 14 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 7 / 957 (0.73%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 7 | 0 | 2 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 2 | 1 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 1 / 16 (6.25%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 1 | 1 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 2 / 16 (12.50%) | 5 / 16 (31.25%) |
| occurrences (all) | 0 | 2 | 7 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 1 / 16 (6.25%) |
| occurrences (all) | 0 | 0 | 1 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 2 / 16 (12.50%) |
| occurrences (all) | 0 | 0 | 2 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 957 (0.00%) | 0 / 16 (0.00%) | 0 / 16 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/30 mcg) | Ph1:5-<12Y:D1-1M After D2/BNT162b2 (30/10 mcg) | Ph1:5-<12Y:D3-1M After D3/BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 11 / 12 (91.67%) | 35 / 38 (92.11%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 4 (75.00%) | 5 / 12 (41.67%) | 6 / 38 (15.79%) |
| occurrences (all) | 5 | 6 | 6 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 0 | 1 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 10 / 12 (83.33%) | 15 / 38 (39.47%) |
| occurrences (all) | 8 | 15 | 15 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 12 (8.33%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 1 | 1 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 3 / 12 (25.00%) | 11 / 38 (28.95%) |
| occurrences (all) | 7 | 4 | 11 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 2 / 12 (16.67%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 2 | 1 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 11 / 12 (91.67%) | 33 / 38 (86.84%) |
| occurrences (all) | 8 | 21 | 33 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 3 / 4 (75.00%) | 1 / 12 (8.33%) | 5 / 38 (13.16%) |
| occurrences (all) | 4 | 1 | 5 |
| Malaise | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 4 / 12 (33.33%) | 1 / 38 (2.63%) |
| occurrences (all) | 4 | 4 | 1 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 0 | 1 |
| Contusion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |

| | | | |
|---|---|---|---|
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 3 / 4 (75.00%) | 6 / 12 (50.00%) | 13 / 38 (34.21%) |
| occurrences (all) | 6 | 8 | 13 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 12 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all) | 1 | 0 | 1 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 0 | 1 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 2 / 4 (50.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 1 / 12 (8.33%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 2 / 12 (16.67%) | 1 / 38 (2.63%) |
| occurrences (all) | 1 | 2 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 0 | 1 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 1 / 38 (2.63%) |
| occurrences (all) | 0 | 0 | 1 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 1 / 4 (25.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 4 (25.00%) | 1 / 12 (8.33%) | 1 / 38 (2.63%) |
| occurrences (all) | 2 | 1 | 1 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 4 / 4 (100.00%) | 1 / 12 (8.33%) | 3 / 38 (7.89%) |
| occurrences (all) | 6 | 1 | 3 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 4 (0.00%) | 0 / 12 (0.00%) | 0 / 38 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph2/3:Bl PCFup:6M-<2Y:D1-1M After D2/Placebo | Ph2/3:BlPCFup:5 -<12Y:D1-1M After D2 or PTD3/BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/Org BNT162b2 10 mcg |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1083 / 1538 (70.42%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 129 / 1538 (8.39%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 150 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 641 / 1538 (41.68%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 879 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 148 / 1538 (9.62%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 170 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 661 / 1538 (42.98%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 916 | 0 | 0 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 78 / 1538 (5.07%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 87 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 40 / 1538 (2.60%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 42 | 0 | 0 |
| Immune system disorders | | | |

| | | | |
|---|---|---|---|
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Concussion | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 506 / 1538 (32.90%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 656 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 138 / 1538 (8.97%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 151 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 55 / 1538 (3.58%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 57 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 110 / 1538 (7.15%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 127 | 0 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 192 / 1538 (12.48%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 230 | 0 | 0 |

| | | | |
|---|---|---|---|
| Neck pain | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 1538 (0.00%) | 0 / 3109 (0.00%) | 0 / 957 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | Ph2/3:Bl PCFup:5-<12Y:TPG:D1-1M After D2/Pb BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:D3-6M After D3/BNT162b2 10 mcg | Ph2/3:Bl OLP:5-<12Y:TPG:D3-1M After D3/Org BNT162b2 10 mcg |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 163 / 260 (62.69%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| General disorders and administration site conditions | | | |
| Axillary pain | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chills (CHILLS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 31 / 260 (11.92%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 33 | 0 | 0 |
| Fatigue | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fatigue (FATIGUE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 105 / 260 (40.38%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 128 | 0 | 0 |
| Injection site bruising | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site discomfort | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site erythema (REDNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 17 / 260 (6.54%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 18 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain (PAIN) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 79 / 260 (30.38%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 98 | 0 | 0 |
| Injection site pain (TENDERNESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling (SWELLING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 14 / 260 (5.38%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 17 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia (FEVER) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 8 / 260 (3.08%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Immune system disorders | | | |
| Seasonal allergy | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Social circumstances | | | |
| Menarche | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Irritability (IRRITABILITY) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Animal bite | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthropod bite | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Foreign body ingestion | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fracture | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin laceration | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Headache (HEADACHE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 77 / 260 (29.62%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 88 | 0 | 0 |
| Presyncope | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Somnolence (DROWSINESS) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Speech disorder developmental | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal discomfort | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhea (DIARRHEA) | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 26 / 260 (10.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 27 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting (VOMITING) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 8 / 260 (3.08%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 9 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash macular | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Arthralgia (JOINT PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 22 / 260 (8.46%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 25 | 0 | 0 |
| Costochondritis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia (MUSCLE PAIN) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 31 / 260 (11.92%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 38 | 0 | 0 |
| Neck pain | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| COVID-19 | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enterobiasis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hand-foot-and-mouth disease | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Periorbital cellulitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 3 / 260 (1.15%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Decreased appetite (DECREASED APPETITE) | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 0 / 260 (0.00%) | 0 / 2410 (0.00%) | 0 / 202 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
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| 10 September 2019 | Amendment 3: Updated to allow an additional 2250 Phase 2/3 selected-dose Participants 5 years of age, to enlarge the size of the pediatric safety database. This has resulted in the total number of participants in this portion of the study increasing to approximately 9000 participants. Included blood draws, procedures, and objectives for potential troponin I testing in participants ≥5 to 12 and ≥12 to 16 years. Added the rationale for collecting serum samples for potential troponin I testing.Revised an objective and corresponding endpoint to describe severe COVID-19 cases in participants in the selected-dose portion of the study. Clarified the process for participants who become eligible for receipt of BNT162b2 or another COVID-19 vaccine prior to Visit 5 (6-month follow-up visit). Added a second definition of symptoms of severe COVID-19 disease per the CDC definition. Clarified instructions on how to unblind participants at the 6-month follow-up visit. Updated information on the recording of nonstudy vaccination and concomitant medications. |
| 05 March 2021 | Amendment 1: Added 2 age groups to the study: participants ≥2 to <5 years and ≥6 months to <2 years of age, to also study safety and immunogenicity in these age groups. Updated efficacy objectives to apply across ages in which immunobridging has been successful, if 22 cases are accrued. Made updates to match Pfizer's response to 04 February 2021 CBER comments regarding this study, ie: Exclusion criterion 3 applied to all study participants rather than just to Phase 1 participants. References to "noninferiority" updated to "immunobridging." Made additions to the exclusion criteria for previous or current diagnosis of MIS-C. Added to the exclusion criteria receipt of any passive antibody therapy specific to COVID-19 within 90 days prior to enrollment. Specified that placebo recipients who decline BNT162b2 will be followed for 24 months (Visits X and Y). Temporary delay of study intervention criteria regarding nonstudy vaccination updated to be most permissive, ie, to allow easier scheduling around childhood routine vaccinations. Added the following symptoms as prompts to complete the COVID-19/MIS-C illness e-diary: Inability to eat/poor feeding in participants <5 years of age; Abdominal pain; Hospitalization due to confirmed COVID-19 infection. Following updates made to the first confirmed COVID-19 case definition to accommodate inclusion of participants 5 years of age: Definition of diarrhea added. Inability to eat/poor feeding in participants 5 years of age added as an additional symptom. Definition of SARS-CoV-2–related hospitalization added. RR and HR required to meet the SARS-CoV-2–related severe case definition specified by participant age. Table 4 inserted. Added that cell-mediated immune responses will be described following isolation of PBMCs in a subset of Phase 2/3 participants ≥10 years of age. Corresponding visit (Visit 3) added approximately<br>7 days after Dose 2. |

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| 06 August 2021 | Amendment 2: Made the following updates in response to commitments made to CBER concerning myocarditis and pericarditis: Insertion of additional row in risk assessment table in risk assessment section. Addition of myocarditis and pericarditis in Adverse Events of Special Interest section. Addition of a procedure to any visit that occurs sooner than 1 month after any vaccination. Addition of an unplanned visit to capture data pertaining to myocarditis and pericarditis. Revised protocol title to reflect the changes in age and dose evaluation.Updated to allow an additional 2250 Phase 2/3 selected-dose participants to enlarge the size of the pediatric safety database. Added Phase 1/2/3 evaluation of lower dose levels for children and young adults with corresponding objectives. Revised the order of Visit 1 activities to clarify when procedures should be conducted in relation to study intervention administration when the visit occurs over 2 consecutive days. Added updates and reformatted activities in the SoA. Removed the requirement to conduct a potential COVID-19 convalescent visit following each potential COVID-19 illness visit. The collection of the blood sample was to support an exploratory endpoint, which will be addressed with external data and thereby reduce burden to participants and caregivers. Added a country-specific appendix that allows flexibility to conduct scheduled follow-up visits in the participant's home, ie, site-arranged home health visits, as permitted per local guidelines (applicable to Poland only). |
| 29 September 2021 | Amendment 4: Revised the success criterion for the efficacy hypotheses to the lower limit of 95% CI 30, in response to regulatory feedback. Added Section 1.1.1, requiring the avoidance of strenuous or endurance exercise 4 days prior to Visit 1 through Visit 1 and from Visit 2 through Visit 3 for the potential troponin I testing subset. Clarified that Phase 2/3 selected-dose participants who originally received active vaccine and are unblinded before Visit 5 will complete the original SoA (Section 1.3.3) before transitioning to the SoA in Section 1.3.3.1. |
| 15 November 2021 | Amendment 5: Based on the 10-µg immunobridging data in the ≥5- to 12-year age group, revised Phase 1/2/3 evaluation of lower dose schedules for children and adolescents. Revised age range for the oldest age group. Revised corresponding objectives, estimands, and endpoints. Revised corresponding SoA and procedures. Revised details in the statistical methods sections. Added flexibility for Visit 5 to be conducted as a telephone visit for the 4500 participants included to enlarge the size of the pediatric safety database, reducing the burden on the participant or participant's parent(s)/legal guardian. Included an exploratory objective to describe the immune response to emerging VOCs. Added the instruction that participants who receive COVID-19 vaccines outside of the study from protocol amendment 5 onwards should be withdrawn to maintain the appropriate assessment of the study intervention. Removed the lifestyle consideration related to strenuous or endurance exercise (potential troponin I testing group only) following regulatory feedback. Updated the appendix for SAE reporting to include guidance on how to report SAEs to Pfizer Safety via an electronic data collection tool. |

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| 04 January 2022 | Amendment 6: The primary immunogenicity analysis demonstrated that the immune response elicited by BNT162b2 in participants ≥2 to 5 years of age (2 doses at 3 µg) did not meet immunobridging criteria when compared to participants 16 to 25 years of age from the C4591001 study. As a result, and given the emerging data in individuals 16 years of age and older, an additional (third) dose of BNT162b2 will be administered to all Phase 1 dose-finding and Phase 2/3 selected-dose participants: Added corresponding objectives, estimands, and endpoints. Added corresponding SoA and procedures. Added details in the statistical methods sections. Cell-mediated immune responses will also be described following isolations of PBMCs in a subset of Phase 2/3 participants who receive a third dose. An additional 4500 Phase 2/3 selected-dose participants ≥6 months to 2 years and ≥2 to 5 years of age are permitted to enroll to enlarge the size of the pediatric safety database. Clarified that participants who decline the opportunity to receive third dose should be withdrawn. Clarified that the interval between the second and third doses will be based on the participant's age at the time of enrollment. Clarified that the dose level of BNT162b2 will be based on age at the time of vaccination. As the asymptomatic efficacy objective is now restricted to participants ≥5 to 12 years of age, in the Phase 2/3 selected-dose portion, participants ≥6 months to 5 years of age who enrolled before protocol amendment 6 will no longer have a blood sample for immunogenicity testing at Visit 5 (6-month follow-up). Time frames for prohibited nonstudy vaccines were simplified. For the option of a 3-µg dose level, an additional unit dose strength was added. For participants 5 years of age, all positive RT-PCR cases confirmed by the central laboratory will undergo BioFire testing. |
| 10 March 2022 | Amendment 7: Given the emerging data in individuals 16 years of age and older, an additional (third) dose of BNT162b2 at least 5 months after Dose 2 to all Phase 2/3 participants enrolled to support obtaining serum samples for potential troponin I testing (≥5 to12 years of age, placebo-controlled, and ≥12 to 16 years of age, open-label):Clarified both symptomatic and asymptomatic COVID-19 infection will result in temporary delay of enrollment, randomization, or study intervention administration. Clarified that the dose interval for Phase 2/3 selected-dose participants enrolled in the ≥2 to 5 years age group who originally received placebo and will turn 5 years of age prior to crossing over to active vaccine will be the same as for the ≥5 to 12 years age group (ie, third dose administered at least 6 months after the second dose). Additional clarification for Phase 2/3 selected-dose parents/legal guardians that decline the blinded third dose. Added flexibility to inclusion and exclusion criteria (based on investigator's judgment) for Phase 1 dose-finding participants when receiving Dose 3. Clarified that, for Phase 1 dose-finding participants, height and weight should be collected once at Visit 1 only as part of the physical examination; likewise, the participant's randomization number and study intervention allocation are obtained using the IRT system at Visit 1 only. The timing of cases for these 2 groups are similar, therefore making it more likely to compare cases of the same variant. Added collection of maternal COVID-19 immunization and breastfeeding data for participants who are ≥6 months to 2 years of age in the Phase 2/3 selected-dose portion of the study. Updated the risk assessment to align with the current version of the IB. |

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| 28 April 2023 | Amendment 8: Updated schedules of assessments and protocol text to identify study visits that no longer need to be completed.Updated study procedures to describe site actions following approval of protocol amendment 8.Removed the lower-dose-evaluation substudy of the protocol. The FDA has approved the request for the lower-dose evaluation postmarketing commitment release in November 2022. Provided further guidance for participants withdrawal from the study for Phase 2/3 selected-dose parents/legal guardians that decline the blinded third dose. Added a statement that participants in Mexico will not self collect nasal swabs per Mexican regulatory request. Clarified that the window for provision of a third dose of BNT162b2 for participants ≥5 years of age to 12 years of age in the US is in line with changing regulatory requirements (emergency use approvals). Removed blood sample collection for immunogenicity testing at certain study visits for Phase 1 dose-finding participants and Phase 2/3 selected-dose participants who are part of the immunogenicity subset to reduce the burden of procedures on participants and caregivers for those enrolling in study C4591048. Secondary/exploratory objectives with corresponding text throughout the protocol removed: To describe the efficacy of prophylactic BNT162b2 against asymptomatic infection in participants ≥5 to 12 years age in the selected-dose portion of the study without evidence of past SARS-CoV-2 infection. To describe the serological responses in Phase 2/3 participants in the selected-dose portion of the study to BNT162b2 at the dose level selected in each age group in cases of: Confirmed COVID-19 with and without coinfection or Confirmed severe COVID-19 or SARS-CoV-2 infection without confirmed COVID-19. Added exploratory objective to describe the incidence of confirmed COVID-19 through the entire study follow-up period. Added corresponding estimands, endpoints, and statistical analysis methods. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported