Clinical trial results:
A Phase 2/3 Randomized, Double-blind, Palivizumab-controlled Study to Evaluate the Safety of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in High-risk Children (MEDLEY)

Summary

EudraCT number	2019-000201-69
Trial protocol	BE LV GB SE DE BG CZ EE HU LT PL FI AT FR ES IT
Global end of trial date	23 June 2023

Results information

Result version number	v1 (current)
This version publication date	04 August 2023
First version publication date	04 August 2023

Trial information

Trial identification

Sponsor protocol code	D5290C00005

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	One MedImmune Way, Gaithersburg, United States, 20878
Public contact	Global Clinical Lead, AstraZeneca, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001784-PIP01-15
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 June 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 June 2023
Global end of trial reached?	Yes
Global end of trial date	23 June 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Study D5290C00005 (MEDLEY) is a pivotal Phase 2/3 randomized, double-blind, palivizumab-controlled study to evaluate the safety, PK, ADA response, and descriptive efficacy for MEDI8897 in high-risk infants eligible to receive palivizumab when entering their first or second RSV season (Season 1 or Season 2, respectively).

Protection of trial subjects:

Each subject was assigned a SID to ensure that personally identifiable information was kept separate from the study data. Subject data that were relevant to the trial, eg, demographic information, physical or mental health condition, diagnosis, comorbidities, laboratory test results, etc. were collected with the subject's informed consent.

The IRB/IEC responsible for each site must review and approve the final study protocol, including the final version of the Informed Consent Form and any other written information and/or materials to be provided to the subjects. The IRB/IEC must also approve all advertising used to recruit subjects for the study.

Before the study was initiated, AstraZeneca/MedImmune ensured that the national regulatory authority in each country had been notified and their approval had been obtained, as required. AstraZeneca/MedImmune provided safety updates/reports according to local requirements, including suspected unexpected serious adverse reactions where relevant, to regulatory authorities, IRB/IEC, and principal investigators.

Background therapy:

MEDI8897 is a recombinant human immunoglobulin G1 kappa (IgG1κ) monoclonal antibody (mAb) directed against the prefusion conformation of the RSV fusion (F) protein. The antibody has been engineered with a triple amino acid substitution (YTE; M257Y/S259T/T261E [M252Y/S254T/T256E, according to the European Union (EU) numbering system]) in the fragment crystallizable (Fc) region to prolong the t1/2, which is expected to provide protection from serious RSV disease for the duration of the RSV season. MEDI8897 neutralizes RSV by binding the prefusion conformation of the RSV F protein at a site distinct from that bound by palivizumab. In preclinical studies, MEDI8897 was > 150 fold more potent than palivizumab in vitro and approximately 9-fold more potent than palivizumab in vivo in the cotton rat model. MEDI8897 is currently under development by MedImmune for the passive immunization of all infants entering their first RSV season and children with CLD or CHD entering their first and second RSV season for the prevention of LRTI caused by RSV. MEDI8897 may provide a cost effective opportunity to protect all infants from RSV disease based on an improvement in potency and the extended t1/2 that is expected to support once-per-RSV-season dosing.

Evidence for comparator:

Palivizumab is an approved RSV prophylaxis, requires 5 once-monthly injections for protection and due to cost is restricted for use only in infants at the greatest risk for morbidity and mortality from RSV.

Actual start date of recruitment	30 July 2019
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	Austria: 1
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Bulgaria: 118
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	Czechia: 9
Country: Number of subjects enrolled	Estonia: 24
Country: Number of subjects enrolled	Finland: 1
Country: Number of subjects enrolled	France: 32
Country: Number of subjects enrolled	Germany: 13
Country: Number of subjects enrolled	Hungary: 27
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	Japan: 33
Country: Number of subjects enrolled	Latvia: 40
Country: Number of subjects enrolled	Lithuania: 16
Country: Number of subjects enrolled	Mexico: 16
Country: Number of subjects enrolled	Poland: 68
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 9
Country: Number of subjects enrolled	Russian Federation: 103
Country: Number of subjects enrolled	Spain: 133
Country: Number of subjects enrolled	Sweden: 3
Country: Number of subjects enrolled	Turkey: 19
Country: Number of subjects enrolled	Ukraine: 49
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	United States: 117
Country: Number of subjects enrolled	South Africa: 73
Worldwide total number of subjects	925
EEA total number of subjects	498

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	848
Newborns (0-27 days)	8
Infants and toddlers (28 days-23 months)	69
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

In Season 1, a total of 960 subjects were screened, of whom 35 were screen failures because they did not meet the eligibility criteria, withdrew consent, or met other reasons for withdrawal.

Period 1

Period 1 title	Season 1
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	MEDI8897

Arm description:

Subjects in MEDI8897 group in Season 1. Season 1 data are reported for MEDI8897, and Palivizumab groups.

Arm type	Experimental
Investigational medicinal product name	MEDI8897
Investigational medicinal product code	MEDI8897
Other name	Nirsevimab
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MEDI8897 50 mg if < 5 kg or 100 mg if >= 5 kg IM

Arm title	Palivizumab

Arm description:

Subjects in Palivizumab group in Season 1. Season 1 data are reported for MEDI8897, and Palivizumab groups.

Arm type	Active comparator
Investigational medicinal product name	Palivizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Palivizumab 15 mg/kg IM

Number of subjects in period 1	MEDI8897	Palivizumab
Started	616	309
Completed	543	263
Not completed	73	46
Adverse event, serious fatal	5	1
Other	6	7
Lost to follow-up	17	7
Withdrawal by parent/guardian	43	28
Due to COVID-19 pandemic	2	3

Period 2

Period 2 title	Season 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	MEDI8897/MEDI8897

Arm description:

CHD/CLD subjects who were randomized to MEDI8897 group in Season 1 and remained in MEDI8897 group in Season 2. Season 2 data are reported for MEDI8897/MEDI8897, Palivizumab/MEDI8897, Palivizumab/Palivizumab groups.

Arm type	Experimental
Investigational medicinal product name	MEDI8897
Investigational medicinal product code	MEDI8897
Other name	Nirsevimab
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MEDI8897 200 mg IM

Arm title	Palivizumab/MEDI8897

Arm description:

CHD/CLD subjects who were randomized to Palivizumab group in Season 1 and re-randomized to MEDI8897 group in Season 2. Season 2 data are reported for MEDI8897/MEDI8897, Palivizumab/MEDI8897, Palivizumab/Palivizumab groups.

Arm type	Experimental
Investigational medicinal product name	MEDI8897
Investigational medicinal product code	MEDI8897
Other name	Nirsevimab
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

MEDI8897 200 mg IM

Arm title	Palivizumab/Palivizumab

Arm description:

CHD/CLD subjects who were randomized to Palivizumab group in Season 1 and re-randomized to Palivizumab group in Season 2. Season 2 data are reported for MEDI8897/MEDI8897, Palivizumab/MEDI8897, Palivizumab/Palivizumab groups.

Arm type	Active comparator
Investigational medicinal product name	Palivizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Palivizumab 15 mg/kg IM

Number of subjects in period 2[1]	MEDI8897/MEDI8897	Palivizumab/MEDI8897	Palivizumab/Palivizumab
Started	180	40	42
Completed	174	39	40
Not completed	6	1	2
Other	2	-	-
Lost to follow-up	1	-	1
Withdrawal by parent/guardian	3	1	1

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: Only CHD/CLD subjects who completed Season 1 entered into Season 2. Preterm subjects completed study at the end of Season 1.

Baseline characteristics

Reporting groups	
Reporting group title	MEDI8897
Reporting group description:	
Subjects in MEDI8897 group in Season 1. Season 1 data are reported for MEDI8897, and Palivizumab groups.	
Reporting group title	Palivizumab
Reporting group description:	
Subjects in Palivizumab group in Season 1. Season 1 data are reported for MEDI8897, and Palivizumab groups.	

Reporting group values	MEDI8897	Palivizumab	Total
Number of subjects	616	309	925
Age categorical			
Age at Season 1 randomization			
Units: Subjects			
Newborns (0-27 days)	46	29	75
Infants (28 days-12 months)	570	280	850
Age Continuous			
Age at Season 1 randomization for Season 1 participants			
Units: Months			
arithmetic mean	3.947	3.840	
standard deviation	± 2.5513	± 2.4608	-
Sex: Female, Male			
Sex summary for Season 1 participants			
Units:			
Female	297	133	430
Male	319	176	495
Chronic lung disease			
CLD summary for Season 1 participants			
Units: Subjects			
Yes	147	70	217
No	469	239	708
Congenital heart disease			
CHD summary for Season 1 participants			
Units: Subjects			
Yes	70	34	104
No	546	275	821

End points

End points reporting groups

Reporting group title	MEDI8897
Reporting group description:	
Subjects in MEDI8897 group in Season 1. Season 1 data are reported for MEDI8897, and Palivizumab groups.	
Reporting group title	Palivizumab
Reporting group description:	
Subjects in Palivizumab group in Season 1. Season 1 data are reported for MEDI8897, and Palivizumab groups.	
Reporting group title	MEDI8897/MEDI8897
Reporting group description:	
CHD/CLD subjects who were randomized to MEDI8897 group in Season 1 and remained in MEDI8897 group in Season 2. Season 2 data are reported for MEDI8897/MEDI8897, Palivizumab/MEDI8897, Palivizumab/Palivizumab groups.	
Reporting group title	Palivizumab/MEDI8897
Reporting group description:	
CHD/CLD subjects who were randomized to Palivizumab group in Season 1 and re-randomized to MEDI8897 group in Season 2. Season 2 data are reported for MEDI8897/MEDI8897, Palivizumab/MEDI8897, Palivizumab/Palivizumab groups.	
Reporting group title	Palivizumab/Palivizumab
Reporting group description:	
CHD/CLD subjects who were randomized to Palivizumab group in Season 1 and re-randomized to Palivizumab group in Season 2. Season 2 data are reported for MEDI8897/MEDI8897, Palivizumab/MEDI8897, Palivizumab/Palivizumab groups.	

Primary: Safety and tolerability of MEDI8897 as assessed by the occurrence of all treatment emergent adverse events (TEAEs) and treatment emergent serious adverse events (TESAEs) and adverse events of special interest (AESIs) and new onset chronic disease (NOCD)

End point title	Safety and tolerability of MEDI8897 as assessed by the occurrence of all treatment emergent adverse events (TEAEs) and treatment emergent serious adverse events (TESAEs) and adverse events of special interest (AESIs) and new onset chronic disease (NOCD)[1]
End point description:	
Safety and tolerability of MEDI8897 will be assessed by the occurrence of all treatment-emergent adverse events (TEAEs), treatment-emergent serious adverse events (TESAEs) , adverse events of special interest (AESIs), and new onset chronic diseases (NOCDs)	
End point type	Primary
End point timeframe:	
360 days post dose	

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: There is no formal hypothesis testing in this study. Only descriptive summaries are provided.

End point values	MEDI8897	MEDI8897/MEDI8897	Palivizumab	Palivizumab/MEDI8897
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	614	180	304	40
Units: Participant				
TEAE|Number of participants with event	444	130	215	31
TESAE|Number of participants with event	80	23	38	4
AESI|Number of participants with event	3	1	0	0
NOCD|Number of participants with event	3	1	0	0

End point values	Palivizumab/Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: Participant				
TEAE|Number of participants with event	29			
TESAE|Number of participants with event	2			
AESI|Number of participants with event	0			
NOCD|Number of participants with event	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Evaluate serum concentrations of MEDI8897 and palivizumab

End point title	Evaluate serum concentrations of MEDI8897 and palivizumab

End point description:

Individual MEDI8897 and palivizumab serum concentration data will be tabulated by treatment group along with descriptive statistics. PK parameters will be estimated using non compartmental analysis, if data permit.

End point type	Secondary

End point timeframe:

360 days post dose

End point values	MEDI8897	MEDI8897/MEDI8897	Palivizumab	Palivizumab/MEDI8897
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	614	180	304	40
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Serum concentration at Day 15	104.75 (± 61.8)	149.38 (± 169.2)	66.43 (± 55.7)	97.70 (± 302.0)

Serum concentration at Day 31	85.35 (± 74.2)	89.71 (± 369.5)	48.10 (± 50.0)	124.89 (± 256.1)
Serum concentration at Day 151	25.38 (± 58.8)	39.86 (± 145.9)	101.56 (± 65.6)	37.95 (± 118.6)

End point values	Palivizumab/Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Serum concentration at Day 15	59.62 (± 102.4)			
Serum concentration at Day 31	57.77 (± 56.3)			
Serum concentration at Day 151	67.66 (± 111.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of anti-drug antibody to MEDI8897 and palivizumab in serum

End point title	Incidence of anti-drug antibody to MEDI8897 and palivizumab in serum

End point description:

The incidence of ADA to MEDI8897 and palivizumab will be assessed and summarized by number and percentage of subjects that are ADA positive by treatment group.

End point type	Secondary

End point timeframe:

360 days post dose

End point values	MEDI8897	MEDI8897/MEDI8897	Palivizumab	Palivizumab/MEDI8897
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	587	180[2]	289	40
Units: Participant				
Any post-baseline ADA positive result	34	21	20	1

Notes:

[2] - Cumulative Season 1 + Season 2 ADA data is reported for MEDI8897/MEDI8897 group

End point values	Palivizumab/Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	42[3]			
Units: Participant				

Any post-baseline ADA positive result	6			

Notes:

[3] - Cumulative Season 1 + Season 2 ADA data is reported for Palivizumab/Palivizumab group

Statistical analyses

No statistical analyses for this end point

Secondary: Assess the descriptive efficacy of MEDI8897 in reducing medically attended LRTI incidence and hospitalization due to Reverse Transcriptase Chain Reaction (RT-PCR) confirmed RSV through 150 days post first dose

End point title	Assess the descriptive efficacy of MEDI8897 in reducing medically attended LRTI incidence and hospitalization due to Reverse Transcriptase Chain Reaction (RT-PCR) confirmed RSV through 150 days post first dose

End point description:

Incidence of medically attended LRTI (inpatient and outpatient) due to RT-PCR-confirmed RSV through 150 days after Dose 1 for season 1 and season 2

End point type	Secondary

End point timeframe:

150 days post dose

End point values	MEDI8897	MEDI8897/MEDI8897	Palivizumab	Palivizumab/MEDI8897
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	616	180	309	40
Units: Participant				
MA RSV LRTI through 150 days post first dose	4	0	3	0
RSV LRTI hospitalization	2	0	2	0

End point values	Palivizumab/Palivizumab			
Subject group type	Reporting group			
Number of subjects analysed	42			
Units: Participant				
MA RSV LRTI through 150 days post first dose	0			
RSV LRTI hospitalization	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Through 360 days post first dose of Season 1 for MEDI8897 and Palivizumab groups, through 360 days post first dose of Season 2 for MEDI8897/MEDI8897, MEDI8897/Palivizumab, and Palivizumab/Palivizumab groups.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	MedDRA25.1

Reporting groups

Reporting group title	Palivizumab/MEDI8897

Reporting group description:

CHD/CLD subjects who received Palivizumab in Season 1 and MEDI8897 in Season 2.

Reporting group title	Palivizumab

Reporting group description:

Subjects who received Palivizumab in Season 1.

Reporting group title	MEDI8897

Reporting group description:

Subjects who received MEDI8897 in Season 1.

Reporting group title	MEDI8897/MEDI8897

Reporting group description:

CHD/CLD subjects who received MEDI8897 in both Season 1 and Season 2.

Reporting group title	Palivizumab/Palivizumab

Reporting group description:

CHD/CLD subjects who received Palivizumab in both Season 1 and Season 2.

Serious adverse events	Palivizumab/MEDI8897	Palivizumab	MEDI8897
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 40 (10.00%)	38 / 304 (12.50%)	80 / 614 (13.03%)
number of deaths (all causes)	0	1	5
number of deaths resulting from adverse events	0	1	5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Cyanosis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
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			
Crying			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Hyperthermia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Pyrexia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Social problem			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Social stay hospitalisation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Anaemic hypoxia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Chylothorax			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Hypoxia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diaphragm muscle weakness			

subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Pulmonary artery stenosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal stenosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Infantile apnoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertensive crisis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Catheterisation cardiac			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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			
Endotracheal intubation complication			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Gastrostomy tube site complication			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Vaccination complication			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Skull fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			

Atrioventricular septal defect			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Atrial septal defect			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Craniosynostosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Vascular malformation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Fallot's tetralogy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block second degree			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			

subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure congestive			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Dyskinesia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nystagmus			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (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
Haemorrhage intracranial			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Syncope			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
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			
Anaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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			
Retinopathy of prematurity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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

Duodenal ulcer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Ascites			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric fistula			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intussusception			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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			
Angioedema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	3 / 614 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Adenovirus infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone abscess			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (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
Bronchiolitis			
subjects affected / exposed	0 / 40 (0.00%)	4 / 304 (1.32%)	11 / 614 (1.79%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Bronchitis			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	5 / 614 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (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	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			

subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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 / 40 (2.50%)	1 / 304 (0.33%)	6 / 614 (0.98%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (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
Dacryocystitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (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
Nasopharyngitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Metapneumovirus bronchiolitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (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	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 40 (2.50%)	2 / 304 (0.66%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (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
Pharyngitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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
Pneumonia			
subjects affected / exposed	2 / 40 (5.00%)	1 / 304 (0.33%)	5 / 614 (0.81%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Rotavirus infection			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
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 / 40 (0.00%)	2 / 304 (0.66%)	4 / 614 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	4 / 304 (1.32%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	3 / 614 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Feeding intolerance			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophagia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Underweight			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (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	MEDI8897/MEDI8897	Palivizumab/Palivizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 180 (12.78%)	2 / 42 (4.76%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Cyanosis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Crying			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperthermia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			
Social problem			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social stay hospitalisation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			

Intermenstrual bleeding			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Apnoea			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemic hypoxia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chylothorax			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diaphragm muscle weakness			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary artery stenosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pleural effusion			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal stenosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infantile apnoea			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary hypertensive crisis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Catheterisation cardiac			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oxygen saturation decreased			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural			

complications			
Endotracheal intubation complication			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrostomy tube site complication			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaccination complication			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skull fracture			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Atrioventricular septal defect			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial septal defect			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Craniosynostosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular malformation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fallot's tetralogy			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Dyskinesia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nystagmus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotonia			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinopathy of prematurity			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ascites			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal fissure			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated inguinal hernia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric fistula			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intussusception			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis viral			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenovirus infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bone abscess			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis norovirus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	3 / 180 (1.67%)	1 / 42 (2.38%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric infection			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dacryocystitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus bronchiolitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis aseptic			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection viral			

subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotavirus infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varicella			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Feeding intolerance			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Feeding disorder			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophagia			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Underweight			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Palivizumab/MEDI8897	Palivizumab	MEDI8897
Total subjects affected by non-serious adverse events			
subjects affected / exposed	31 / 40 (77.50%)	211 / 304 (69.41%)	435 / 614 (70.85%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Haemangioma			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	2
Vascular disorders			
Pelvic venous thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Cyanosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Capillary fragility			

subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Surgical and medical procedures			
Ear tube insertion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Ear operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dacryocystorhinostomy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Adenoidectomy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Gastrostomy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Tongue tie operation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Orchidopexy			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Myringotomy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Developmental delay			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Catheter site haematoma			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Calcinosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Discomfort			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	2	0
Drug tolerance			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Medical device site rash			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Medical device site irritation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Injection site reaction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Injection site induration			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	2
Incarcerated hernia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Impaired healing			

subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Hyperthermia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Fever neonatal			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	1	0	1
Drug withdrawal syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Peripheral swelling			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Vaccination site urticaria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Vaccination site swelling			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Vaccination site reaction			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Vaccination site erythema			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Swelling			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1

Secretion discharge			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Pyrexia			
subjects affected / exposed	9 / 40 (22.50%)	43 / 304 (14.14%)	81 / 614 (13.19%)
occurrences (all)	12	57	109
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Milk allergy			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	6 / 614 (0.98%)
occurrences (all)	0	3	6
Hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Food allergy			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	6 / 614 (0.98%)
occurrences (all)	0	3	6
Drug hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Nutritional supplement allergy			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Scrotal dermatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Vulvovaginal discomfort			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Balanoposthitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Enlarged clitoris			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Genital labial adhesions			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	2
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	1	0	2
Allergic cough			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Aspiration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Asthma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Atelectasis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	1	0	1
Bronchial hyperreactivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	3 / 614 (0.49%)
occurrences (all)	0	1	3
Bronchospasm			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	3
Catarrh			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	3 / 614 (0.49%)
occurrences (all)	0	1	4
Chronic respiratory disease			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Pulmonary hypertension			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	2 / 614 (0.33%)
occurrences (all)	0	3	2
Oropharyngeal pain			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	2 / 614 (0.33%)
occurrences (all)	0	2	2
Nasal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	4 / 304 (1.32%)	7 / 614 (1.14%)
occurrences (all)	0	5	7
Nasal congestion			
subjects affected / exposed	1 / 40 (2.50%)	13 / 304 (4.28%)	41 / 614 (6.68%)
occurrences (all)	1	16	53
Lung opacity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Laryngeal stenosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	2	1
Chylothorax			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Cough			

subjects affected / exposed	0 / 40 (0.00%)	6 / 304 (1.97%)	16 / 614 (2.61%)
occurrences (all)	0	7	18
Cough variant asthma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	1 / 40 (2.50%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	1	1	2
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Tonsillar hypertrophy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	4 / 40 (10.00%)	12 / 304 (3.95%)	23 / 614 (3.75%)
occurrences (all)	6	14	28
Rhinitis allergic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Respiration abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pulmonary oedema			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	2 / 614 (0.33%)
occurrences (all)	0	2	2
Pulmonary hypertensive crisis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	3 / 614 (0.49%)
occurrences (all)	0	1	3
Anxiety			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Drug dependence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	6 / 614 (0.98%)
occurrences (all)	0	3	11
Restlessness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Staring			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Sleep terror			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hypertransaminasaemia			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Jaundice			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Sphincter of Oddi dysfunction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Blood albumin decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Blood potassium decreased			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Body temperature abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	4 / 614 (0.65%)
occurrences (all)	0	0	4
Cardiac murmur			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Coronavirus test positive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Herpes simplex test positive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Echocardiogram			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	2
Enterovirus test positive			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Escherichia test positive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Haemophilus test positive			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Head circumference abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Crystal urine present			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Human rhinovirus test positive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Respiratory syncytial virus test positive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 40 (2.50%)	3 / 304 (0.99%)	4 / 614 (0.65%)
occurrences (all)	1	3	4
Weight abnormal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1

SARS-CoV-2 test negative			
subjects affected / exposed	3 / 40 (7.50%)	10 / 304 (3.29%)	19 / 614 (3.09%)
occurrences (all)	5	15	40
Injury, poisoning and procedural complications			
Chillblains			
subjects affected / exposed	1 / 40 (2.50%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	1	1	0
Accidental exposure to product			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	2 / 614 (0.33%)
occurrences (all)	0	3	3
Arthropod sting			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Eye injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Clavicle fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	2
Foreign body in respiratory tract			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Head injury			

subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	4 / 614 (0.65%)
occurrences (all)	0	1	4
Intestinal anastomosis complication			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Lip injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Penis injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Post procedural complication			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Post procedural haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Radial head dislocation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Re-opening of ductus arteriosus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	1	0	3
Subcutaneous haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Wound dehiscence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Vaccination complication			

subjects affected / exposed	0 / 40 (0.00%)	19 / 304 (6.25%)	25 / 614 (4.07%)
occurrences (all)	0	25	36
Traumatic haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Tooth avulsion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Tongue injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Anomalous pulmonary venous connection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Brachycephaly			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Left ventricle outflow tract obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Cerebral palsy			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Cleft palate			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Congenital choroid plexus cyst			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Congenital nystagmus			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Congenital oral malformation			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	0 / 614 (0.00%)
occurrences (all)	0	2	0
Cryptorchism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Cystic fibrosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dacryostenosis congenital			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	0 / 614 (0.00%)
occurrences (all)	0	2	0
Dysmorphism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Eyelid ptosis congenital			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hydrocele			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Laryngomalacia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Cerebellar hypoplasia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Phimosis			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	1 / 614 (0.16%)
occurrences (all)	0	2	1
Plagiocephaly			

subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	1 / 614 (0.16%)
occurrences (all)	0	3	1
Vascular malformation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrioventricular block complete			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Atrial fibrillation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Atrioventricular block			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Atrioventricular block second degree			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Cardiac failure			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	0 / 614 (0.00%)
occurrences (all)	0	3	0
Cardiac failure chronic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Cardiac septal hypertrophy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Low cardiac output syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Mitral valve incompetence			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Pericardial effusion			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	3

Right atrial dilatation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	0 / 614 (0.00%)
occurrences (all)	0	2	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Tricuspid valve incompetence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	2
Bundle branch block right			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Cerebral ventricle dilatation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Diplegia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dyskinesia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dystonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Infant irritability			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Motor developmental delay			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Posthaemorrhagic hydrocephalus			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Seizure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Haemorrhage intracranial			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Speech disorder developmental			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Vocal cord paralysis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			

Neutropenia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	0 / 614 (0.00%)
occurrences (all)	0	2	0
Pancytopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Monocytosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	0 / 40 (0.00%)	5 / 304 (1.64%)	12 / 614 (1.95%)
occurrences (all)	0	5	12
Anaemia neonatal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	5 / 614 (0.81%)
occurrences (all)	0	3	5
Lymphadenitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Ear and labyrinth disorders			
Eustachian tube dysfunction			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Cerumen impaction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Hypoacusis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Noninfective myringitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Otorrhoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Neurosensory hypoacusis			
subjects affected / exposed	1 / 40 (2.50%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	1	1	1
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Anisometropia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1

Astigmatism			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	1 / 614 (0.16%)
occurrences (all)	0	2	1
Blepharitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Blepharospasm			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Chalazion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Choroidal effusion			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Eye allergy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	0 / 40 (0.00%)	4 / 304 (1.32%)	1 / 614 (0.16%)
occurrences (all)	0	5	2
Eye inflammation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Eyelid ptosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Eyelid function disorder			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0

Heterophoria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Retinopathy of prematurity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Retinopathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Periorbital swelling			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Myopia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Inflammation of lacrimal passage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hypermetropia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Strabismus			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Anal erythema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Enterocolitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	1	0	2
Enteritis			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	3 / 614 (0.49%)
occurrences (all)	0	3	4
Dysphagia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	1	0	3
Dyschezia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dysbiosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	3
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	2 / 40 (5.00%)	11 / 304 (3.62%)	29 / 614 (4.72%)
occurrences (all)	3	12	33
Constipation			
subjects affected / exposed	2 / 40 (5.00%)	20 / 304 (6.58%)	37 / 614 (6.03%)
occurrences (all)	2	28	39
Aphthous ulcer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	4 / 614 (0.65%)
occurrences (all)	0	0	4
Ankyloglossia acquired			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Anal fissure haemorrhage			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Faecaloma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	3
Faeces discoloured			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Faeces pale			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Faeces soft			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Inguinal hernia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	3 / 614 (0.49%)
occurrences (all)	0	2	3
Infantile spitting up			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Infantile colic			
subjects affected / exposed	0 / 40 (0.00%)	6 / 304 (1.97%)	9 / 614 (1.47%)
occurrences (all)	0	6	9
Ileus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Haematochezia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	2
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 40 (0.00%)	9 / 304 (2.96%)	13 / 614 (2.12%)
occurrences (all)	0	9	13
Gastrointestinal pain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	1 / 614 (0.16%)
occurrences (all)	0	2	1
Gastric fistula			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Flatulence			
subjects affected / exposed	0 / 40 (0.00%)	5 / 304 (1.64%)	1 / 614 (0.16%)
occurrences (all)	0	5	1
Small intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	4 / 40 (10.00%)	11 / 304 (3.62%)	15 / 614 (2.44%)
occurrences (all)	5	14	17
Umbilical hernia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	2 / 614 (0.33%)
occurrences (all)	0	2	2
Toothache			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	0 / 614 (0.00%)
occurrences (all)	0	3	0
Tongue erythema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 40 (0.00%)	16 / 304 (5.26%)	31 / 614 (5.05%)
occurrences (all)	0	19	35
Stomatitis			

subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	1	0	2
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Acne infantile			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	0 / 40 (0.00%)	7 / 304 (2.30%)	14 / 614 (2.28%)
occurrences (all)	0	7	15
Dermatitis contact			
subjects affected / exposed	1 / 40 (2.50%)	1 / 304 (0.33%)	11 / 614 (1.79%)
occurrences (all)	1	1	12
Dermatitis diaper			
subjects affected / exposed	0 / 40 (0.00%)	6 / 304 (1.97%)	28 / 614 (4.56%)
occurrences (all)	0	6	29
Drug eruption			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 40 (0.00%)	4 / 304 (1.32%)	14 / 614 (2.28%)
occurrences (all)	0	4	15
Eczema			
subjects affected / exposed	0 / 40 (0.00%)	11 / 304 (3.62%)	14 / 614 (2.28%)
occurrences (all)	0	14	14
Eczema asteatotic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Eczema infantile			
subjects affected / exposed	0 / 40 (0.00%)	5 / 304 (1.64%)	10 / 614 (1.63%)
occurrences (all)	0	5	11
Eczema nummular			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0

Asteatosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Blister			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Butterfly rash			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	7 / 614 (1.14%)
occurrences (all)	0	0	8
Dermatitis allergic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Erythema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Skin discolouration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Erythrosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Excessive granulation tissue			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Miliaria			
subjects affected / exposed	0 / 40 (0.00%)	11 / 304 (3.62%)	18 / 614 (2.93%)
occurrences (all)	0	12	18
Papule			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1

Perioral dermatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Rash			
subjects affected / exposed	2 / 40 (5.00%)	9 / 304 (2.96%)	21 / 614 (3.42%)
occurrences (all)	2	9	21
Rash erythematous			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	3
Rash macular			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Rash maculo-papular			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	4 / 614 (0.65%)
occurrences (all)	0	3	4
Rash neonatal			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	3
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	3 / 614 (0.49%)
occurrences (all)	0	3	4
Erythema toxicum neonatorum			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Skin irritation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	2 / 614 (0.33%)
occurrences (all)	0	2	2

Urticaria papular			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Vesicoureteric reflux			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Oliguria			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Nephrolithiasis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Hydronephrosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Acute kidney injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Chest wall haematoma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Growth failure			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Myosclerosis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1

Myositis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Rickets			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Torticollis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Infections and infestations			
Candida nappy rash			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Acarodermatitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	4 / 614 (0.65%)
occurrences (all)	0	0	4
Acute sinusitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Adenoiditis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Anal fungal infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Bacterial blepharitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Body tinea			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Bronchiolitis			

subjects affected / exposed	0 / 40 (0.00%)	9 / 304 (2.96%)	22 / 614 (3.58%)
occurrences (all)	0	12	27
Bronchitis			
subjects affected / exposed	4 / 40 (10.00%)	10 / 304 (3.29%)	20 / 614 (3.26%)
occurrences (all)	7	16	28
COVID-19			
subjects affected / exposed	3 / 40 (7.50%)	2 / 304 (0.66%)	8 / 614 (1.30%)
occurrences (all)	3	2	8
Candida infection			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	2 / 614 (0.33%)
occurrences (all)	0	5	2
Catheter site infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Exanthema subitum			
subjects affected / exposed	1 / 40 (2.50%)	4 / 304 (1.32%)	9 / 614 (1.47%)
occurrences (all)	1	4	9
Clostridium difficile infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	1 / 40 (2.50%)	10 / 304 (3.29%)	25 / 614 (4.07%)
occurrences (all)	1	12	31
Conjunctivitis bacterial			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	2
Coronavirus infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Croup infectious			
subjects affected / exposed	1 / 40 (2.50%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	1	1	1
Dacryocystitis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Dermatitis infected			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Device related sepsis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Ear infection			
subjects affected / exposed	1 / 40 (2.50%)	5 / 304 (1.64%)	5 / 614 (0.81%)
occurrences (all)	1	6	8
Enterobiasis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	2	0	0
Enterovirus infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Cellulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Eye infection			
subjects affected / exposed	1 / 40 (2.50%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	1	2	0
Gingivitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	1 / 40 (2.50%)	15 / 304 (4.93%)	19 / 614 (3.09%)
occurrences (all)	1	15	21
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Gastroenteritis norovirus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Gastroenteritis rotavirus			

subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis sapovirus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	2 / 40 (5.00%)	2 / 304 (0.66%)	3 / 614 (0.49%)
occurrences (all)	2	2	3
Gastroenteritis yersinia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Gastrointestinal viral infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Genital infection fungal			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Giardiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	7 / 614 (1.14%)
occurrences (all)	0	3	7
Impetigo			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Human herpesvirus 6 infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Infectious mononucleosis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	2 / 40 (5.00%)	7 / 304 (2.30%)	11 / 614 (1.79%)
occurrences (all)	2	12	12
Laryngopharyngitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Lice infestation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	3 / 40 (7.50%)	10 / 304 (3.29%)	18 / 614 (2.93%)
occurrences (all)	4	13	21
Lower respiratory tract infection viral			
subjects affected / exposed	1 / 40 (2.50%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	1	0	3
Molluscum contagiosum			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	7 / 40 (17.50%)	39 / 304 (12.83%)	57 / 614 (9.28%)
occurrences (all)	16	50	84
Oral candidiasis			
subjects affected / exposed	0 / 40 (0.00%)	6 / 304 (1.97%)	10 / 614 (1.63%)
occurrences (all)	0	7	10
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 40 (0.00%)	6 / 304 (1.97%)	15 / 614 (2.44%)
occurrences (all)	0	6	15
Herpes virus infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Hordeolum			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	3
Infection			

subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	2	1
Otitis externa			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	0 / 614 (0.00%)
occurrences (all)	0	3	0
Otitis media			
subjects affected / exposed	3 / 40 (7.50%)	11 / 304 (3.62%)	27 / 614 (4.40%)
occurrences (all)	3	14	37
Otitis media acute			
subjects affected / exposed	5 / 40 (12.50%)	14 / 304 (4.61%)	16 / 614 (2.61%)
occurrences (all)	6	18	20
Otitis media chronic			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Otitis media viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Otosalpingitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Parasitic gastroenteritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	2 / 40 (5.00%)	8 / 304 (2.63%)	23 / 614 (3.75%)
occurrences (all)	2	8	29
Pharyngitis streptococcal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pharyngotonsillitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pneumonia			

subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	4 / 614 (0.65%)
occurrences (all)	0	3	4
Pneumonia aspiration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Rotavirus infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	2
Rhinitis			
subjects affected / exposed	6 / 40 (15.00%)	40 / 304 (13.16%)	75 / 614 (12.21%)
occurrences (all)	8	64	109
Roseola			
subjects affected / exposed	1 / 40 (2.50%)	5 / 304 (1.64%)	8 / 614 (1.30%)
occurrences (all)	1	5	8
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	2
Rash pustular			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Pyoderma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pyelonephritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pustule			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1

Post procedural infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pneumonia parainfluenzae viral			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Pneumonia bacterial			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	6 / 614 (0.98%)
occurrences (all)	0	3	8
Sepsis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Salmonellosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Staphylococcal skin infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Subglottic laryngitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Superinfection viral			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0

Suspected COVID-19			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Tinea infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	4
Tonsillitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Tracheitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Tracheobronchitis			
subjects affected / exposed	0 / 40 (0.00%)	3 / 304 (0.99%)	1 / 614 (0.16%)
occurrences (all)	0	3	1
Upper respiratory tract infection			
subjects affected / exposed	8 / 40 (20.00%)	77 / 304 (25.33%)	148 / 614 (24.10%)
occurrences (all)	12	131	235
Sinusitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Yersinia infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	0 / 614 (0.00%)
occurrences (all)	0	0	0
Vulvitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	8 / 40 (20.00%)	14 / 304 (4.61%)	33 / 614 (5.37%)
occurrences (all)	8	15	42
Viral rhinitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Viral rash			
subjects affected / exposed	1 / 40 (2.50%)	3 / 304 (0.99%)	7 / 614 (1.14%)
occurrences (all)	1	3	7

Viral pharyngitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Viral infection			
subjects affected / exposed	1 / 40 (2.50%)	2 / 304 (0.66%)	2 / 614 (0.33%)
occurrences (all)	1	2	2
Varicella zoster virus infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Varicella			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	5 / 614 (0.81%)
occurrences (all)	0	0	5
Urinary tract infection bacterial			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	3 / 614 (0.49%)
occurrences (all)	0	0	3
Electrolyte imbalance			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Underweight			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Feeding disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Feeding intolerance			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	0 / 614 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	2 / 614 (0.33%)
occurrences (all)	0	1	2
Hypoglycaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Hypokalaemia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	2 / 614 (0.33%)
occurrences (all)	0	3	2
Hypomagnesaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Hypophagia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 40 (0.00%)	1 / 304 (0.33%)	1 / 614 (0.16%)
occurrences (all)	0	1	1
Malnutrition			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Failure to thrive			
subjects affected / exposed	0 / 40 (0.00%)	2 / 304 (0.66%)	1 / 614 (0.16%)
occurrences (all)	0	2	1
Vitamin B12 deficiency			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2
Zinc deficiency			

subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	1 / 614 (0.16%)
occurrences (all)	0	0	1
Weight gain poor			
subjects affected / exposed	0 / 40 (0.00%)	0 / 304 (0.00%)	2 / 614 (0.33%)
occurrences (all)	0	0	2

Non-serious adverse events	MEDI8897/MEDI8897	Palivizumab/Palivizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	129 / 180 (71.67%)	29 / 42 (69.05%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Haemangioma			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Pelvic venous thrombosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Haematoma			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Cyanosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Capillary fragility			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			

Ear tube insertion			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Ear operation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dacryocystorhinostomy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Adenoidectomy			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Gastrostomy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Tongue tie operation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Orchidopexy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Myringotomy			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Developmental delay			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Catheter site haematoma			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Calcinosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Discomfort			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Drug tolerance			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Oedema			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Medical device site rash			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Medical device site irritation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Injection site induration			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Injection site erythema			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Incarcerated hernia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Impaired healing			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hyperthermia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Fever neonatal			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Fatigue				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Drug withdrawal syndrome				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Peripheral swelling				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Vaccination site urticaria				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Vaccination site swelling				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Vaccination site reaction				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Vaccination site erythema				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Systemic inflammatory response syndrome				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Swelling				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Secretion discharge				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Pyrexia				
subjects affected / exposed	23 / 180 (12.78%)	6 / 42 (14.29%)		
occurrences (all)	37	14		

Immune system disorders			
Seasonal allergy			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Milk allergy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypersensitivity			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Food allergy			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Drug hypersensitivity			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Nutritional supplement allergy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Scrotal dermatitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal discomfort			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Balanoposthitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Enlarged clitoris			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Genital labial adhesions			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			

Adenoidal hypertrophy			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Allergic cough			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Aspiration			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Asthma			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Atelectasis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Bronchial hyperreactivity			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Bronchopulmonary dysplasia			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	4	0	
Bronchospasm			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Catarrh			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	4	0	
Chronic respiratory disease			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Pulmonary hypertension			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Pleural effusion			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Nasal obstruction			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	2	
Nasal congestion			
subjects affected / exposed	4 / 180 (2.22%)	0 / 42 (0.00%)	
occurrences (all)	5	0	
Lung opacity			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Laryngeal stenosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypoxia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Chylothorax			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cough			
subjects affected / exposed	6 / 180 (3.33%)	0 / 42 (0.00%)	
occurrences (all)	6	0	
Cough variant asthma			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Wheezing			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Upper respiratory tract inflammation			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	4	0	
Upper respiratory tract congestion			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Tonsillar hypertrophy			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Stridor			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	14 / 180 (7.78%)	2 / 42 (4.76%)	
occurrences (all)	25	4	
Rhinitis allergic			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Respiration abnormal			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Pulmonary oedema			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Pulmonary hypertensive crisis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Anxiety			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Drug dependence			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Restlessness			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Staring			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Sleep terror			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Product issues			
Device dislocation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Jaundice			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Sphincter of Oddi dysfunction			

subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Blood albumin decreased			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Blood potassium decreased			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Body temperature abnormal			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Body temperature increased			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Cardiac murmur			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Coronavirus test positive			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Herpes simplex test positive			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Echocardiogram			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Enterovirus test positive			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Escherichia test positive			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Haemophilus test positive			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Head circumference abnormal			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Crystal urine present			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Human rhinovirus test positive			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count decreased			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Respiratory syncytial virus test positive			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
SARS-CoV-2 test positive			
subjects affected / exposed	4 / 180 (2.22%)	2 / 42 (4.76%)	
occurrences (all)	4	2	
Weight abnormal			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
SARS-CoV-2 test negative			
subjects affected / exposed	4 / 180 (2.22%)	1 / 42 (2.38%)	
occurrences (all)	10	1	
Injury, poisoning and procedural complications			

Chillblains			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Accidental exposure to product			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Arthropod bite			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Arthropod sting			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Eye injury			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Skin laceration			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Concussion			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Clavicle fracture			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Fall			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Foreign body in respiratory tract			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Head injury			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Intestinal anastomosis complication			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Lip injury			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Penis injury			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Post procedural complication			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Post procedural haematoma			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Radial head dislocation			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Re-opening of ductus arteriosus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Contusion			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Subcutaneous haematoma			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Subdural haematoma			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Wound dehiscence			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Vaccination complication			
subjects affected / exposed	1 / 180 (0.56%)	2 / 42 (4.76%)	
occurrences (all)	1	2	
Traumatic haematoma			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	

Tooth avulsion			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Tongue injury			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
Thermal burn			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Anomalous pulmonary venous connection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Brachycephaly			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Left ventricle outflow tract obstruction			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cerebral palsy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cleft palate			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Congenital choroid plexus cyst			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Congenital nystagmus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Congenital oral malformation			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cryptorchism			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cystic fibrosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dacryostenosis congenital			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dysmorphism			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Eyelid ptosis congenital			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hydrocele			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Laryngomalacia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cerebellar hypoplasia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Phimosis			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Plagiocephaly			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Vascular malformation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			

Atrioventricular block complete			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Atrial fibrillation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Atrioventricular block			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Atrioventricular block second degree			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cardiac failure			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Cardiac failure chronic			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cardiac septal hypertrophy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Low cardiac output syndrome			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Mitral valve incompetence			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Pericardial effusion			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Right atrial dilatation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Sinus bradycardia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Supraventricular tachycardia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Tachycardia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Tricuspid valve incompetence			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Bundle branch block right			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Ataxia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Cerebral ventricle dilatation			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Diplegia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dyskinesia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dystonia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Febrile convulsion			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Somnolence			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Hypotonia			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Infant irritability			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Motor developmental delay			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Posthaemorrhagic hydrocephalus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Psychomotor hyperactivity			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Seizure			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Speech disorder developmental			
subjects affected / exposed	0 / 180 (0.00%)	2 / 42 (4.76%)	
occurrences (all)	0	2	
Tremor			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Vocal cord paralysis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Pancytopenia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	

Thrombocytopenia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Thrombocytosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Monocytosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Anaemia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Anaemia neonatal			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Heparin-induced thrombocytopenia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Iron deficiency anaemia			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Lymphadenitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Lymphadenopathy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Eustachian tube dysfunction			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Ear pain			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Deafness			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Cerumen impaction			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypoacusis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
External ear inflammation			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Noninfective myringitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Otorrhoea			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Tympanic membrane perforation			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Neurosensory hypoacusis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Anisometropia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Astigmatism			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Blepharitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	2	0	

Blepharospasm				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Cataract				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Chalazion				
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)		
occurrences (all)	1	0		
Choroidal effusion				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Conjunctivitis allergic				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Eye allergy				
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)		
occurrences (all)	1	0		
Eye discharge				
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)		
occurrences (all)	1	0		
Eye inflammation				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Eyelid ptosis				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Eyelid function disorder				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Heterophoria				
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)		
occurrences (all)	1	0		
Retinopathy of prematurity				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		

Retinopathy			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Periorbital swelling			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Myopia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Inflammation of lacrimal passage			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Hypermetropia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Strabismus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Anal erythema			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Enterocolitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Enteritis			

subjects affected / exposed	3 / 180 (1.67%)	1 / 42 (2.38%)	
occurrences (all)	5	1	
Dysphagia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Dyschezia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dysbiosis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	10 / 180 (5.56%)	7 / 42 (16.67%)	
occurrences (all)	12	7	
Constipation			
subjects affected / exposed	5 / 180 (2.78%)	2 / 42 (4.76%)	
occurrences (all)	5	2	
Aphthous ulcer			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Ankyloglossia acquired			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Anal fissure haemorrhage			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Anal fissure			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Faecaloma			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Faeces discoloured			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Faeces pale			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Faeces soft			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Oesophagitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Inguinal hernia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Infantile spitting up			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Infantile colic			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Ileus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Haematochezia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal pain			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Gastritis			

subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Gastric fistula			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Functional gastrointestinal disorder			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
Small intestinal obstruction			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	6 / 180 (3.33%)	3 / 42 (7.14%)	
occurrences (all)	7	8	
Umbilical hernia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Tongue erythema			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Teething			
subjects affected / exposed	7 / 180 (3.89%)	2 / 42 (4.76%)	
occurrences (all)	7	2	
Stomatitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Acne infantile			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dermatitis atopic			
subjects affected / exposed	3 / 180 (1.67%)	1 / 42 (2.38%)	
occurrences (all)	4	1	
Dermatitis contact			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	2	1	
Dermatitis diaper			
subjects affected / exposed	8 / 180 (4.44%)	1 / 42 (2.38%)	
occurrences (all)	9	1	
Drug eruption			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Eczema			
subjects affected / exposed	4 / 180 (2.22%)	1 / 42 (2.38%)	
occurrences (all)	4	1	
Eczema asteatotic			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Eczema infantile			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Eczema nummular			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Asteatosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Blister			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Butterfly rash			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Decubitus ulcer			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Dermatitis allergic			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Skin discolouration			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Erythrosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Excessive granulation tissue			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Miliaria			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Papule			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Perioral dermatitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	4 / 180 (2.22%)	1 / 42 (2.38%)	
occurrences (all)	4	1	

Rash erythematous			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Rash macular			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Rash neonatal			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Rash papular			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Erythema toxicum neonatorum			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Skin irritation			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	2	
Skin mass			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Urticaria papular			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Vesicoureteric reflux			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Oliguria			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Nephrolithiasis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hydronephrosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Acute kidney injury			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Chest wall haematoma			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Growth failure			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Myosclerosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Myositis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Rickets			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Torticollis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Candida nappy rash			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Acarodermatitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Acute sinusitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Adenoiditis			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Adenovirus infection			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Anal fungal infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Bacterial blepharitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Body tinea			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Bronchiolitis			
subjects affected / exposed	9 / 180 (5.00%)	2 / 42 (4.76%)	
occurrences (all)	11	2	
Bronchitis			
subjects affected / exposed	7 / 180 (3.89%)	1 / 42 (2.38%)	
occurrences (all)	7	1	

COVID-19			
subjects affected / exposed	14 / 180 (7.78%)	5 / 42 (11.90%)	
occurrences (all)	14	5	
Candida infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Catheter site infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Exanthema subitum			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Clostridium difficile infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	11 / 180 (6.11%)	3 / 42 (7.14%)	
occurrences (all)	11	3	
Conjunctivitis bacterial			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Conjunctivitis viral			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Coronavirus infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Croup infectious			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Dacryocystitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Dermatitis infected			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Device related sepsis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	2 / 180 (1.11%)	2 / 42 (4.76%)	
occurrences (all)	3	2	
Enterobiasis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Enterovirus infection			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
Cellulitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Eye infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Gingivitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	11 / 180 (6.11%)	2 / 42 (4.76%)	
occurrences (all)	19	3	
Gastroenteritis adenovirus			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis norovirus			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis sapovirus			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	

Gastroenteritis viral			
subjects affected / exposed	4 / 180 (2.22%)	0 / 42 (0.00%)	
occurrences (all)	4	0	
Gastroenteritis yersinia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal bacterial overgrowth			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal viral infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Genital infection fungal			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Giardiasis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Fungal skin infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Impetigo			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Human herpesvirus 6 infection			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Infectious mononucleosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Laryngitis			
subjects affected / exposed	3 / 180 (1.67%)	1 / 42 (2.38%)	
occurrences (all)	4	1	

Laryngopharyngitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Lice infestation			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
Lower respiratory tract infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Molluscum contagiosum			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
Nasopharyngitis			
subjects affected / exposed	26 / 180 (14.44%)	9 / 42 (21.43%)	
occurrences (all)	55	15	
Oral candidiasis			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Hand-foot-and-mouth disease			
subjects affected / exposed	9 / 180 (5.00%)	2 / 42 (4.76%)	
occurrences (all)	9	2	
Herpes virus infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Otitis externa			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Otitis media			
subjects affected / exposed	12 / 180 (6.67%)	2 / 42 (4.76%)	
occurrences (all)	16	3	
Otitis media acute			
subjects affected / exposed	11 / 180 (6.11%)	2 / 42 (4.76%)	
occurrences (all)	19	4	
Otitis media chronic			
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)	
occurrences (all)	1	1	
Otitis media viral			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Otosalpingitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Parasitic gastroenteritis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	7 / 180 (3.89%)	0 / 42 (0.00%)	
occurrences (all)	9	0	
Pharyngitis streptococcal			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Pharyngotonsillitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Pneumonia			
subjects affected / exposed	2 / 180 (1.11%)	1 / 42 (2.38%)	
occurrences (all)	2	1	
Pneumonia aspiration			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	2	0	

Rotavirus infection				
subjects affected / exposed	1 / 180 (0.56%)	1 / 42 (2.38%)		
occurrences (all)	1	1		
Respiratory tract infection viral				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Rhinitis				
subjects affected / exposed	29 / 180 (16.11%)	6 / 42 (14.29%)		
occurrences (all)	38	16		
Roseola				
subjects affected / exposed	3 / 180 (1.67%)	2 / 42 (4.76%)		
occurrences (all)	3	2		
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Rash pustular				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Pyoderma				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Pyelonephritis				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Pustule				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Post procedural infection				
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)		
occurrences (all)	0	0		
Pneumonia parainfluenzae viral				

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Pneumonia haemophilus			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Pneumonia bacterial			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Skin candida			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Sepsis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Salmonellosis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Staphylococcal skin infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Subglottic laryngitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Superinfection viral			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Suspected COVID-19			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Tinea infection			

subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Tonsillitis			
subjects affected / exposed	4 / 180 (2.22%)	1 / 42 (2.38%)	
occurrences (all)	4	1	
Tracheitis			
subjects affected / exposed	2 / 180 (1.11%)	1 / 42 (2.38%)	
occurrences (all)	2	1	
Tracheobronchitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	48 / 180 (26.67%)	9 / 42 (21.43%)	
occurrences (all)	86	26	
Sinusitis			
subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	4	0	
Yersinia infection			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Vulvitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	14 / 180 (7.78%)	2 / 42 (4.76%)	
occurrences (all)	18	2	
Viral rhinitis			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Viral rash			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Viral pharyngitis			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Viral infection			

subjects affected / exposed	2 / 180 (1.11%)	0 / 42 (0.00%)	
occurrences (all)	2	0	
Varicella zoster virus infection			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Varicella			
subjects affected / exposed	3 / 180 (1.67%)	0 / 42 (0.00%)	
occurrences (all)	3	0	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Dehydration			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Electrolyte imbalance			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Underweight			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Feeding disorder			
subjects affected / exposed	0 / 180 (0.00%)	1 / 42 (2.38%)	
occurrences (all)	0	1	
Feeding intolerance			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

Hyperkalaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypoglycaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypokalaemia			
subjects affected / exposed	1 / 180 (0.56%)	0 / 42 (0.00%)	
occurrences (all)	1	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Hypophagia			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Iron deficiency			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Malnutrition			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Failure to thrive			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Zinc deficiency			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	
Weight gain poor			
subjects affected / exposed	0 / 180 (0.00%)	0 / 42 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 March 2021	The principal reason for this amendment was to update the sample size for target enrollment, introduce a primary analysis and Season 2 analysis to allow earlier assessment of Season 1 and Season 2 data, respectively, and add a description about the process to safeguard the blind.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported