



Clinical trial results:

A Phase 3, Open-label, Single-Arm Trial to Evaluate the Safety, Tolerability, and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine in Children With Sickle Cell Disease Previously Immunized With 23-valent Pneumococcal Polysaccharide Vaccine

Summary

| | |
|--------------------------|-------------------------|
| EudraCT number | 2009-011396-77 |
| Trial protocol | FR GB IT Outside EU/EEA |
| Global end of trial date | 28 March 2013 |

Results information

| | |
|--------------------------------|----------------|
| Result version number | v1 (current) |
| This version publication date | 29 June 2016 |
| First version publication date | 01 August 2015 |

Trial information

Trial identification

| | |
|-----------------------|------------------------|
| Sponsor protocol code | B1851013 (6096A1-3014) |
|-----------------------|------------------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00918580 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., +1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-000036-PIP01-07 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

Results analysis stage

| | |
|--|---------------|
| Analysis stage | Final |
| Date of interim/final analysis | 04 June 2013 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 March 2013 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immune response 1 month after 2 doses of 13-valent pneumococcal conjugate vaccine (13vPnC) given 6 months apart compared to 1 month after 1 dose of 13vPnC as measured by fold rise in serotype specific immunoglobulin G (IgG) geometric mean concentrations (GMCs) in children with sickle cell disease (SCD) who had been previously vaccinated with at least 1 dose of 23-valent pneumococcal polysaccharide vaccine (23vPS).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 03 November 2009 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Efficacy, Safety |
| Long term follow-up duration | 12 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | United Kingdom: 27 |
| Country: Number of subjects enrolled | France: 9 |
| Country: Number of subjects enrolled | Italy: 11 |
| Country: Number of subjects enrolled | Saudi Arabia: 3 |
| Country: Number of subjects enrolled | Lebanon: 56 |
| Country: Number of subjects enrolled | Egypt: 23 |
| Country: Number of subjects enrolled | United States: 29 |
| Worldwide total number of subjects | 158 |
| EEA total number of subjects | 47 |

Notes:

Subjects enrolled per age group

| | |
|--|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| | |
|--|-----|
| wk | |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 53 |
| Adolescents (12-17 years) | 105 |
| 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:

This study was conducted in the United States of America (USA), United Kingdom, Italy, Lebanon, Egypt, France, and Saudi Arabia. Children with sickle cell disease, of 6 years to less than 18 years of age, previously immunized with 23vPS at least 6 months ago, were enrolled in this study.

Period 1

| | |
|------------------------------|------------------------------|
| Period 1 title | Up to 6-month Follow-up (FU) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|-----------|--------|
| Arm title | 13vPnC |
|-----------|--------|

Arm description:

Subjects previously immunized with 23vPS received 2 single 0.5 milliliter (mL) doses of 13vPnC intramuscular injection, 6 months apart.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | 13-valent pneumococcal conjugate vaccine |
| Investigational medicinal product code | 13vPnC |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart.

| Number of subjects in period 1 | 13vPnC |
|----------------------------------|--------------------|
| Started | 158 |
| Vaccinated Dose 1 | 158 |
| Vaccinated Dose 2 | 146 ^[1] |
| Completed | 147 |
| Not completed | 11 |
| Consent withdrawn by subject | 2 |
| 'Parent/Legal Guardian Request ' | 2 |
| Adverse event, non-fatal | 1 |
| 'Failed to Return ' | 1 |
| Lost to follow-up | 5 |

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: This milestone included 1 subject who withdrew before Dose 2 (protocol violation) but completed 6-month follow-up period.

Period 2

| | |
|------------------------------|-------------------------------|
| Period 2 title | After 6-month FU to 1-year FU |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------|--------|
| Arm title | 13vPnC |
|------------------|--------|

Arm description:

Subjects previously immunized with 23vPS received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart in Period 1.

| | |
|---|-----------------|
| Arm type | No intervention |
| No investigational medicinal product assigned in this arm | |

| Number of subjects in period 2 | 13vPnC |
|---------------------------------------|--------|
| Started | 147 |
| Continued After 6-Month FU | 89 |
| Completed | 87 |
| Not completed | 60 |
| 'Did Not Continue After 6-Month FU' | 58 |
| 'Failed to Return' | 2 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------|
| Reporting group title | 13vPnC |
|-----------------------|--------|

Reporting group description:

Subjects previously immunized with 23vPS received 2 single 0.5 milliliter (mL) doses of 13vPnC intramuscular injection, 6 months apart.

| Reporting group values | 13vPnC | Total | |
|---|----------------|-------|--|
| Number of subjects | 158 | 158 | |
| Age categorical Units: Subjects | | | |
| Age continuous Units: years arithmetic mean standard deviation | 13.3 ± 3.08 | - | |
| Gender categorical Units: Subjects | | | |
| Female | 76 | 76 | |
| Male | 82 | 82 | |

End points

End points reporting groups

| | |
|---|--------|
| Reporting group title | 13vPnC |
| Reporting group description: Subjects previously immunized with 23vPS received 2 single 0.5 milliliter (mL) doses of 13vPnC intramuscular injection, 6 months apart. | |
| Reporting group title | 13vPnC |
| Reporting group description: Subjects previously immunized with 23vPS received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart in Period 1. | |

Primary: Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 1 Month After 13vPnC Dose 1 to 1 Month After 13vPnC Dose 2

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|--|---|
| End point title | Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 1 Month After 13vPnC Dose 1 to 1 Month After 13vPnC Dose 2 ^[1] |
| End point description: GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from 1 month after 13vPnC Dose 1 to 1 month after 13vPnC Dose 2 were computed using logarithmically transformed assay results. Confidence interval (CI) for GMFR were back transformations of a CI based on Student t distribution for mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both 1 month after 13vPnC Dose 1 and after 13vPnC Dose 2 blood draws. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. Here "N" signifies subjects with determinate IgG antibody concentration for the given serotype at both the time points 1 Month After 13vPnC Dose 1 and 1 Month After 13vPnC Dose 2 blood draws. Subjects may be represented in more than 1 category. | |
| End point type | Primary |
| End point timeframe: 1 Month After 13vPnC Dose 1, 1 Month After 13vPnC Dose 2 | |

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: Only descriptive data was planned to be reported.

| End point values | 13vPnC | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 ^[2] | | | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 4 (N = 137) | 0.75 (0.66 to 0.84) | | | |
| Serotype 6B (N = 136) | 0.89 (0.78 to 1.02) | | | |
| Serotype 9V (N = 136) | 0.82 (0.75 to 0.91) | | | |
| Serotype 14 (N = 137) | 0.75 (0.67 to 0.85) | | | |
| Serotype 18C (N = 137) | 0.7 (0.62 to 0.8) | | | |
| Serotype 19F (N = 136) | 1.05 (0.91 to 1.2) | | | |

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|------------------------|---------------------|--|--|--|
| Serotype 23F (N = 135) | 0.91 (0.77 to 1.08) | | | |
| Serotype 1 (N = 137) | 0.88 (0.77 to 0.99) | | | |
| Serotype 3 (N = 134) | 0.82 (0.75 to 0.9) | | | |
| Serotype 5 (N = 136) | 0.9 (0.82 to 0.98) | | | |
| Serotype 6A (N = 136) | 0.95 (0.82 to 1.1) | | | |
| Serotype 7F (N = 137) | 0.75 (0.67 to 0.85) | | | |
| Serotype 19A (N = 137) | 0.83 (0.74 to 0.93) | | | |

Notes:

[2] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1

| | |
|-----------------|---|
| End point title | Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1 |
|-----------------|---|

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from before 13vPnC Dose 1 to 1 month after 13vPnC Dose 1 were computed using logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on Student t distribution for mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from before 13vPnC Dose 1 and 1 month after 13vPnC Dose 1 blood draws. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subjects with a determinate IgG antibody concentration for given serotype from before 13vPnC Dose 1 and 1 month after 13vPnC Dose 1 blood draws. Subjects may be represented in more than 1 category.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1

| End point values | 13vPnC | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 ^[3] | | | |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 4 (N = 136) | 6.91 (5.27 to 9.06) | | | |
| Serotype 6B (N = 137) | 4.72 (3.8 to 5.85) | | | |
| Serotype 9V (N = 138) | 3.1 (2.6 to 3.7) | | | |
| Serotype 14 (N = 138) | 5.5 (4.05 to 7.46) | | | |

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|------------------------|---------------------|--|--|--|
| Serotype 18C (N = 137) | 5.58 (4.47 to 6.97) | | | |
| Serotype 19F (N = 134) | 4.76 (3.77 to 6.03) | | | |
| Serotype 23F (N = 137) | 6.58 (5.12 to 8.46) | | | |
| Serotype 1 (N = 129) | 3.6 (2.9 to 4.46) | | | |
| Serotype 3 (N = 133) | 2.03 (1.78 to 2.31) | | | |
| Serotype 5 (N = 138) | 1.74 (1.56 to 1.94) | | | |
| Serotype 6A (N = 132) | 4.1 (3.32 to 5.05) | | | |
| Serotype 7F (N = 137) | 4.38 (3.62 to 5.3) | | | |
| Serotype 19A (N = 138) | 3.28 (2.73 to 3.96) | | | |

Notes:

[3] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 2 to 1 Month After 13vPnC Dose 2

| | |
|-----------------|---|
| End point title | Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From Before 13vPnC Dose 2 to 1 Month After 13vPnC Dose 2 |
|-----------------|---|

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from before 13vPnC Dose 2 to 1 month after 13vPnC Dose 2 were computed using logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on Student t distribution for mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from before 13vPnC Dose 2 and 1 month after 13vPnC Dose 2 blood draws. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with a determinate IgG antibody concentration for given serotype from before 13vPnC Dose 2 and 1 month after 13vPnC Dose 2 blood draws. Subjects may be represented in more than 1 category.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before 13vPnC Dose 2, 1 month after 13vPnC Dose 2

| End point values | 13vPnC | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 ^[4] | | | |
| Units: Fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 4 (N = 137) | 1.86 (1.69 to 2.04) | | | |

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|------------------------|---------------------|--|--|--|
| Serotype 6B (N = 137) | 1.8 (1.69 to 2.03) | | | |
| Serotype 9V (N = 136) | 1.48 (1.37 to 1.59) | | | |
| Serotype 14 (N = 137) | 1.24 (1.15 to 1.35) | | | |
| Serotype 18C (N = 137) | 1.47 (1.34 to 1.62) | | | |
| Serotype 19F (N = 135) | 2.08 (1.85 to 2.34) | | | |
| Serotype 23F (N = 135) | 2.04 (1.75 to 2.37) | | | |
| Serotype 1 (N = 136) | 1.73 (1.57 to 1.92) | | | |
| Serotype 3 (N = 133) | 1.36 (1.25 to 1.47) | | | |
| Serotype 5 (N = 135) | 1.3 (1.22 to 1.39) | | | |
| Serotype 6A (N = 133) | 1.8 (1.6 to 2.02) | | | |
| Serotype 7F (N = 137) | 1.75 (1.61 to 1.9) | | | |
| Serotype 19A (N = 137) | 1.48 (1.36 to 1.61) | | | |

Notes:

[4] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 13vPnC Dose 1 to 13vPnC Dose 2

| | |
|-----------------|---|
| End point title | Ratio of Geometric Mean Fold Rise (GMFR) in Serotype-Specific Pneumococcal Immunoglobulin G (IgG) From 13vPnC Dose 1 to 13vPnC Dose 2 |
|-----------------|---|

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were computed using the logarithmically transformed assay results for Dose 1 (after Dose 1/before Dose 1) and for Dose 2 (after Dose 2/before Dose 2). CI for the ratio of GMFR (Dose 2/Dose 1) were back transformations of a CI based on the Student t distribution for the mean logarithm of the measures (Dose 2 – Dose 1). Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with a determinate IgG antibody concentration for given serotype at before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2 and 1 month after 13vPnC Dose 2 blood draws. Subjects may be represented in more than 1 category.

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|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2, 1 month after 13vPnC Dose 2

| End point values | 13vPnC | | | |
|--|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 ^[5] | | | |
| Units: Ratio of GMFR | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 4 (N = 135) | 0.26 (0.2 to 0.35) | | | |
| Serotype 6B (N = 136) | 0.38 (0.29 to 0.49) | | | |
| Serotype 9V (N = 136) | 0.49 (0.41 to 0.59) | | | |
| Serotype 14 (N = 137) | 0.22 (0.16 to 0.31) | | | |
| Serotype 18C (N = 136) | 0.26 (0.21 to 0.34) | | | |
| Serotype 19F (N = 132) | 0.44 (0.34 to 0.57) | | | |
| Serotype 23F (N = 135) | 0.32 (0.24 to 0.43) | | | |
| Serotype 1 (N = 127) | 0.47 (0.37 to 0.59) | | | |
| Serotype 3 (N = 130) | 0.66 (0.58 to 0.75) | | | |
| Serotype 5 (N = 135) | 0.75 (0.66 to 0.85) | | | |
| Serotype 6A (N = 127) | 0.45 (0.35 to 0.58) | | | |
| Serotype 7F (N = 136) | 0.39 (0.32 to 0.49) | | | |
| Serotype 19A (N = 137) | 0.45 (0.36 to 0.55) | | | |

Notes:

[5] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody

| | |
|-----------------|---|
| End point title | Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody |
|-----------------|---|

End point description:

Antibody GMC for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) CIs were evaluated. Geometric means were calculated using all subjects with available data for the specified blood draw. CI for GMC were back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with determinate IgG antibody concentration for the given serotype at specified time point. Subjects may be represented in more than 1 category.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2, 1 month after 13vPnC Dose 2

| End point values | 13vPnC | | | |
|--|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 ^[6] | | | |
| Units: microgram per milliliter (mcg/mL) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Before 13vPnC Dose 1: Serotype 4 (N = 136) | 1.01 (0.8 to 1.27) | | | |
| Before 13vPnC Dose 1: Serotype 6B (N = 138) | 5.79 (4.89 to 6.87) | | | |
| Before 13vPnC Dose 1: Serotype 9V (N = 138) | 3.01 (2.56 to 3.53) | | | |
| Before 13vPnC Dose 1: Serotype 14 (N = 138) | 6.3 (4.78 to 8.3) | | | |
| Before 13vPnC Dose 1: Serotype 18C (N = 137) | 1.4 (1.14 to 1.73) | | | |
| Before 13vPnC Dose 1: Serotype 19F (N = 134) | 4.46 (3.6 to 5.53) | | | |
| Before 13vPnC Dose 1: Serotype 23F (N = 138) | 2.8 (2.38 to 3.3) | | | |
| Before 13vPnC Dose 1: Serotype 1 (N = 129) | 1.57 (1.26 to 1.95) | | | |
| Before 13vPnC Dose 1: Serotype 3 (N = 133) | 1.02 (0.83 to 1.25) | | | |
| Before 13vPnC Dose 1: Serotype 5 (N = 138) | 4.14 (3.58 to 4.78) | | | |
| Before 13vPnC Dose 1: Serotype 6A (N = 132) | 4.62 (3.91 to 5.46) | | | |
| Before 13vPnC Dose 1: Serotype 7F (N = 137) | 2.16 (1.8 to 2.59) | | | |
| Before 13vPnC Dose 1: Serotype 19A (N = 138) | 8.16 (7.03 to 9.48) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 4 (N = 138) | 6.85 (5.55 to 8.44) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 6B (N= 137) | 27.25 (22.09 to 33.61) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 9V (N= 138) | 9.31 (7.83 to 11.07) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 14 (N = 138) | 34.63 (27.77 to 43.18) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 18C (N= 138) | 7.83 (6.42 to 9.54) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 19F (N= 138) | 20.4 (16.03 to 25.95) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 23F (N= 137) | 18.25 (14.52 to 22.95) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 1 (N = 138) | 5.24 (4.3 to 6.39) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 3 (N = 138) | 2.04 (1.76 to 2.38) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 5 (N = 138) | 7.19 (6.19 to 8.35) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 6A (N = 138) | 17.61 (14.16 to 21.91) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 7F (N = 138) | 9.46 (8.17 to 10.94) | | | |

| | | | | |
|--|------------------------|--|--|--|
| 1 Month After 13vPnC Dose 1: Serotype 19A (N= 138) | 26.82 (22.16 to 32.46) | | | |
| Before 13vPnC Dose 2: Serotype 4 (N = 138) | 2.77 (2.29 to 3.35) | | | |
| Before 13vPnC Dose 2: Serotype 6B (N = 138) | 13.67 (11.23 to 16.63) | | | |
| Before 13vPnC Dose 2: Serotype 9V (N = 138) | 5.19 (4.41 to 6.09) | | | |
| Before 13vPnC Dose 2: Serotype 14 (N = 138) | 21.07 (17.29 to 25.67) | | | |
| Before 13vPnC Dose 2: Serotype 18C (N = 138) | 3.73 (3.1 to 4.49) | | | |
| Before 13vPnC Dose 2: Serotype 19F (N = 137) | 10.34 (8.32 to 12.85) | | | |
| Before 13vPnC Dose 2: Serotype 23F (N = 137) | 8.07 (6.63 to 9.83) | | | |
| Before 13vPnC Dose 2: Serotype 1 (N = 137) | 2.65 (2.21 to 3.19) | | | |
| Before 13vPnC Dose 2: Serotype 3 (N = 135) | 1.27 (1.06 to 1.52) | | | |
| Before 13vPnC Dose 2: Serotype 5 (N = 137) | 4.91 (4.26 to 5.66) | | | |
| Before 13vPnC Dose 2: Serotype 6A (N = 135) | 9.05 (7.48 to 10.95) | | | |
| Before 13vPnC Dose 2: Serotype 7F (N = 138) | 4.09 (3.52 to 4.74) | | | |
| Before 13vPnC Dose 2: Serotype 19A (N = 138) | 15.13 (12.73 to 17.98) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 4 (N = 137) | 5.09 (4.28 to 6.04) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 6B (N= 137) | 24.52 (20.48 to 29.35) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 9V (N= 136) | 7.46 (6.46 to 8.61) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 14 (N = 137) | 26.19 (22.11 to 31.03) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 18C (N= 137) | 5.44 (4.64 to 6.38) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 19F (N= 136) | 20.56 (17.15 to 24.63) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 23F (N= 135) | 16.18 (13.27 to 19.73) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 1 (N = 137) | 4.51 (3.82 to 5.32) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 3 (N = 134) | 1.67 (1.42 to 1.97) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 5 (N = 136) | 6.33 (5.58 to 7.17) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 6A (N = 136) | 16.37 (13.65 to 19.64) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 7F (N = 137) | 7.06 (6.2 to 8.04) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 19A (N= 137) | 22.19 (18.94 to 25.99) | | | |

Notes:

[6] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

Secondary: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Year After 13vPnC Dose 2

| | |
|-----------------|--|
| End point title | Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Year After 13vPnC Dose 2 |
|-----------------|--|

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) are presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) CIs were evaluated. Geometric means were calculated using all subjects with available data for the specified blood draw. CI for GMC were back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Analysis was done on the evaluable immunogenicity population at 1 year follow up-eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subjects with a determinate IgG antibody concentration for given serotype. Subjects may be represented in more than 1 category.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

1 year after 13vPnC Dose 2

| End point values | 13vPnC | | | |
|--|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 81 ^[7] | | | |
| Units: mcg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 4 (N = 81) | 1.94 (1.51 to 2.48) | | | |
| Serotype 6B (N = 81) | 11.77 (9.43 to 14.71) | | | |
| Serotype 9V (N = 81) | 4.5 (3.61 to 5.62) | | | |
| Serotype 14 (N = 81) | 15.89 (12.47 to 20.26) | | | |
| Serotype 18C (N = 81) | 2.64 (2.03 to 3.42) | | | |
| Serotype 19F (N = 81) | 9.87 (7.5 to 13) | | | |
| Serotype 23F (N = 81) | 7.7 (6.15 to 9.63) | | | |
| Serotype 1 (N = 79) | 2.12 (1.65 to 2.71) | | | |
| Serotype 3 (N = 67) | 1.01 (0.77 to 1.33) | | | |
| Serotype 5 (N = 81) | 4.38 (3.58 to 5.37) | | | |
| Serotype 6A (N = 81) | 7.94 (6.45 to 9.77) | | | |
| Serotype 7F (N = 81) | 3.47 (2.84 to 4.25) | | | |
| Serotype 19A (N = 81) | 13.3 (10.62 to 16.65) | | | |

Notes:

[7] - Number of subjects analyzed signifies the evaluable immunogenicity population at 1-year follow-up.

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT)

| | |
|---|--|
| End point title | Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) |
| End point description: Antibody GMTs as measured by OPA assay for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). GMT and corresponding 2-sided 95% CIs were evaluated. CIs for the GMTs are back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the titers. GMTs were calculated using all subjects with available data for the specified blood draw. Analysis was done on the evaluable immunogenicity population- eligible subjects who received all study vaccinations; had valid, determinate assay result; blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subject with determinate OPA antibody titer for the given serotype at specified time point. Subjects may be represented in more than 1 category. | |
| End point type | Secondary |
| End point timeframe: Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1, before 13vPnC Dose 2, 1 month after 13vPnC Dose 2 | |

| End point values | 13vPnC | | | |
|--|-----------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 138 ^[8] | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Before 13vPnC Dose 1: Serotype 4 (N = 105) | 215 (129.6 to 357.2) | | | |
| Before 13vPnC Dose 1: Serotype 6B (N = 105) | 626 (377.5 to 1037.4) | | | |
| Before 13vPnC Dose 1: Serotype 9V (N = 109) | 234 (137.6 to 398.7) | | | |
| Before 13vPnC Dose 1: Serotype 14 (N = 115) | 628 (425.8 to 925.7) | | | |
| Before 13vPnC Dose 1: Serotype 18C (N = 95) | 426 (235.7 to 771.4) | | | |
| Before 13vPnC Dose 1: Serotype 19F (N = 96) | 94 (55 to 160.7) | | | |
| Before 13vPnC Dose 1: Serotype 23F (N = 106) | 34 (21.5 to 54.8) | | | |
| Before 13vPnC Dose 1: Serotype 1 (N = 131) | 7 (5.7 to 8.8) | | | |
| Before 13vPnC Dose 1: Serotype 3 (N = 107) | 13 (10.1 to 17.5) | | | |
| Before 13vPnC Dose 1: Serotype 5 (N = 131) | 10 (7.8 to 13.9) | | | |

| | | | | |
|--|-------------------------|--|--|--|
| Before 13vPnC Dose 1: Serotype 6A (N = 116) | 246 (149 to 404.8) | | | |
| Before 13vPnC Dose 1: Serotype 7F (N = 120) | 344 (220.5 to 537.9) | | | |
| Before 13vPnC Dose 1: Serotype 19A (N = 127) | 137 (100 to 187.4) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 4 (N = 108) | 2670 (2128.1 to 3351.1) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 6B (N= 116) | 7535 (6320.5 to 8983.5) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 9V (N= 103) | 2312 (1684 to 3172.8) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 14 (N = 117) | 2288 (1906.6 to 2745) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 18C (N= 103) | 4326 (3250.3 to 5756.8) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 19F (N = 89) | 1429 (1043.5 to 1957.3) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 23F (N= 106) | 1607 (1227.4 to 2102.7) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 1 (N = 123) | 56 (41 to 77.4) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 3 (N = 112) | 115 (93 to 142.1) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 5 (N = 121) | 277 (198.4 to 385.8) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 6A (N = 117) | 7845 (6581.6 to 9349.9) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 7F (N = 123) | 3348 (2881.9 to 3888.5) | | | |
| 1 Month After 13vPnC Dose 1: Serotype 19A (N =118) | 1449 (1164.2 to 1804.3) | | | |
| Before 13vPnC Dose 2: Serotype 4 (N = 104) | 1331 (1013.9 to 1748.1) | | | |
| Before 13vPnC Dose 2: Serotype 6B (N = 108) | 4174 (3513 to 4958.3) | | | |
| Before 13vPnC Dose 2: Serotype 9V (N = 99) | 1445 (1051.7 to 1985.5) | | | |
| Before 13vPnC Dose 2: Serotype 14 (N = 106) | 1652 (1347.8 to 2024.1) | | | |
| Before 13vPnC Dose 2: Serotype 18C (N = 101) | 1928 (1281.1 to 2901) | | | |
| Before 13vPnC Dose 2: Serotype 19F (N = 92) | 516 (338.8 to 785.5) | | | |
| Before 13vPnC Dose 2: Serotype 23F (N = 94) | 897 (619 to 1300.4) | | | |
| Before 13vPnC Dose 2: Serotype 1 (N = 107) | 23 (17.1 to 32.3) | | | |
| Before 13vPnC Dose 2: Serotype 3 (N = 120) | 56 (45.5 to 69.9) | | | |
| Before 13vPnC Dose 2: Serotype 5 (N = 107) | 98 (69.2 to 140.2) | | | |
| Before 13vPnC Dose 2: Serotype 6A (N = 113) | 4005 (3350.6 to 4786.3) | | | |
| Before 13vPnC Dose 2: Serotype 7F (N = 112) | 1791 (1427 to 2248.6) | | | |
| Before 13vPnC Dose 2: Serotype 19A (N = 108) | 677 (544.4 to 843.1) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 4 (N = 105) | 3051 (2536.7 to 3670.3) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 6B (N= 107) | 7601 (6392.6 to 9038.6) | | | |

| | | | | |
|--|-------------------------|--|--|--|
| 1 Month After 13vPnC Dose 2: Serotype 9V (N = 96) | 3467 (2784 to 4317.6) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 14 (N = 110) | 2081 (1770.5 to 2446) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 18C (N= 103) | 5271 (4267.8 to 6510.1) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 19F (N = 89) | 1507 (1139.9 to 1992.2) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 23F (N= 105) | 2330 (1880.4 to 2887) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 1 (N = 106) | 78 (59.5 to 101.2) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 3 (N = 109) | 105 (87.2 to 127.2) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 5 (N = 118) | 273 (213.9 to 349.2) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 6A (N = 111) | 7633 (6439.6 to 9048.6) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 7F (N = 114) | 3723 (3276.2 to 4230.1) | | | |
| 1 Month After 13vPnC Dose 2: Serotype 19A (N= 115) | 1314 (1084.4 to 1592.6) | | | |

Notes:

[8] - Number of subjects analyzed signifies the evaluable immunogenicity population.

Statistical analyses

No statistical analyses for this end point

Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Year After 13vPnC Dose 2

| | |
|-----------------|---|
| End point title | Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Year After 13vPnC Dose 2 |
|-----------------|---|

End point description:

Antibody GMTs as measured by OPA assay for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F). GMT and corresponding 2-sided 95% CIs were evaluated. CIs for the GMTs are back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the titers. GMTs were calculated using all subjects with available data for the specified blood draw. Analysis was done on the evaluable immunogenicity population at 1-year follow up- eligible subjects who received all study vaccinations; had valid and determinate assay result; had blood drawn within pre-specified time-frames; had no major protocol violation. "N" signifies subjects with determinate OPA antibody titer for the given serotype. Subjects may be represented in more than 1 category.

| | |
|----------------------|----------------------------|
| End point type | Secondary |
| End point timeframe: | 1 year after 13vPnC Dose 2 |

| | | | | |
|--|-------------------|--|--|--|
| End point values | 13vPnC | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 81 ^[9] | | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |

| | | | | |
|-----------------------|-------------------------|--|--|--|
| Serotype 4 (N = 58) | 1107 (764.4 to 1602.2) | | | |
| Serotype 6B (N = 59) | 3412 (2746.4 to 4238.7) | | | |
| Serotype 9V (N = 66) | 1690 (1157.8 to 2465.5) | | | |
| Serotype 14 (N = 64) | 1595 (1281.6 to 1984.9) | | | |
| Serotype 18C (N = 59) | 1604 (1107.2 to 2324.2) | | | |
| Serotype 19F (N = 55) | 620 (376.6 to 1020.4) | | | |
| Serotype 23F (N = 58) | 924 (654.2 to 1306.1) | | | |
| Serotype 1 (N = 73) | 25 (17.5 to 35.4) | | | |
| Serotype 3 (N = 72) | 31 (22.6 to 42.6) | | | |
| Serotype 5 (N = 71) | 102 (70.5 to 148) | | | |
| Serotype 6A (N = 72) | 2485 (1921.2 to 3214.3) | | | |
| Serotype 7F (N = 73) | 2166 (1861.4 to 2519.3) | | | |
| Serotype 19A (N = 73) | 589 (449.4 to 771.1) | | | |

Notes:

[9] - Number of subjects analyzed signifies the evaluable immunogenicity population at 1-year follow-up.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 1

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 1 |
|-----------------|---|

End point description:

Specific local reactions were prompted for each day using an electronic diary. Redness and Swelling were scaled as: Any (redness present or swelling present); Mild (less than [$<$]2.5 centimeters [cm] for subjects aged 6 to $<$ 12 years, 2.5 to 5.0 cm for subjects aged greater than or equal to [\geq] 12 years); Moderate (2.5 to 7.0 cm for subjects aged 6 to $<$ 12 years and 5.1 to 10.0 cm for subjects aged \geq 12 years); Severe ($>$ 7 cm for subjects aged 6 to $<$ 12 years and $>$ 10 cm for subjects aged \geq 12 years). Pain was scaled as: Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Safety population Dose 1- all subjects who received Dose 1 of study vaccine, had safety data available. "N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subjects may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Within 7 days after 13vPnC Dose 1

| End point values | 13vPnC | | | |
|-------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 158 ^[10] | | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Pain: Any (N = 144) | 89.6 | | | |
| Pain: Mild (N = 132) | 81.8 | | | |
| Pain: Moderate (N = 113) | 56.6 | | | |
| Pain: Severe (N = 90) | 11.1 | | | |
| Redness: Any (N = 93) | 23.7 | | | |
| Redness: Mild (N = 93) | 20.4 | | | |
| Redness: Moderate (N = 90) | 8.9 | | | |
| Redness: Severe (N = 87) | 1.1 | | | |
| Swelling: Any (N = 108) | 49.1 | | | |
| Swelling: Mild (N = 101) | 37.6 | | | |
| Swelling: Moderate (N = 100) | 26 | | | |
| Swelling: Severe (N = 87) | 1.1 | | | |

Notes:

[10] - Number of subjects analyzed signifies the safety population for Dose 1.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 2

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Prespecified Local Reactions: 13vPnC Dose 2 |
|-----------------|---|

End point description:

Specific local reactions were prompted for each day using an electronic diary. Redness and Swelling were scaled as: Any (redness present or swelling present); Mild (less than <2.5 centimeters [cm] for subjects aged 6 to <12 years, 2.5 to 5.0 cm for subjects aged ≥ 12 years); Moderate (2.5 to 7.0 cm for subjects aged 6 to <12 years and 5.1 to 10.0 cm for subjects aged ≥12 years); Severe (>7 cm for subjects aged 6 to <12 years and >10 cm for subjects aged ≥12 years). Pain was scaled as: Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Safety population Dose 2- all subjects who received Dose 2 of study vaccine and had safety data available. "N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subject may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Within 7 days after 13vPnC Dose 2

| End point values | 13vPnC | | | |
|-------------------------------|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 140 ^[11] | | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Pain: Any (N = 111) | 85.6 | | | |
| Pain: Mild (N = 103) | 77.7 | | | |
| Pain: Moderate (N = 82) | 53.7 | | | |

| | | | | |
|-----------------------------|------|--|--|--|
| Pain: Severe (N = 69) | 15.9 | | | |
| Redness: Any (N = 67) | 26.9 | | | |
| Redness: Mild (N = 66) | 15.2 | | | |
| Redness: Moderate (N = 64) | 14.1 | | | |
| Redness: Severe (N = 63) | 0 | | | |
| Swelling: Any (N = 84) | 53.6 | | | |
| Swelling: Mild (N = 77) | 37.7 | | | |
| Swelling: Moderate (N = 73) | 35.6 | | | |
| Swelling: Severe (N = 63) | 0 | | | |

Notes:

[11] - Number of subjects analyzed signifies the safety population for Dose 2.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 1

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 1 |
|-----------------|---|

End point description:

Specific systemic events (fever ≥ 38 degrees Celsius[C], vomiting, diarrhea, headache, fatigue, muscle pain, joint pain, use of antipyretic medications) were reported for each day using an electronic diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any(symptom present); Mild(did not interfere with activity); Moderate(some interference); Severe(prevented routine daily activity). Vomiting was scaled as: Any(vomiting present); Mild(1-2 times in 24 hours); Moderate(>2 times in 24 hours); Severe(required intravenous hydration). Diarrhea was scaled as: Any(diarrhea present); Mild(2-3 loose stools in 24 hours); Moderate(4-5 loose stools 24 hours); Severe(≥ 6 loose stools in 24 hours). Safety population Dose 1- all subjects who received Dose 1 of study vaccine, had safety data available. "N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subjects may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Within 7 days after 13vPnC Dose 1

| End point values | 13vPnC | | | |
|---|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 158 ^[12] | | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever: ≥ 38 , ≤ 38.4 degrees C (N = 81) | 13.6 | | | |
| Fever: >38.4 , ≤ 38.9 degrees C (N = 82) | 7.3 | | | |
| Fever: >38.9 , ≤ 40 degrees C (N = 79) | 3.8 | | | |
| Fever: >40 degrees C (N = 79) | 1.3 | | | |
| Vomiting: Any (N = 91) | 15.4 | | | |
| Vomiting: Mild (N = 89) | 11.2 | | | |
| Vomiting: Moderate (N = 90) | 6.7 | | | |
| Vomiting: Severe (N = 87) | 0 | | | |
| Diarrhea: Any (N = 90) | 13.3 | | | |
| Diarrhea: Mild (N = 87) | 6.9 | | | |

| | | | | |
|--|------|--|--|--|
| Diarrhea: Moderate (N = 90) | 6.7 | | | |
| Diarrhea: Severe (N = 87) | 2.3 | | | |
| Headache: Any (N = 110) | 53.6 | | | |
| Headache: Mild (N = 105) | 42.9 | | | |
| Headache: Moderate (N = 101) | 34.7 | | | |
| Headache: Severe (N = 92) | 12 | | | |
| Fatigue: Any (N = 118) | 66.1 | | | |
| Fatigue: Mild (N = 108) | 48.1 | | | |
| Fatigue: Moderate (N = 104) | 44.2 | | | |
| Fatigue: Severe (N = 90) | 14.4 | | | |
| Muscle Pain: Any (N = 127) | 74.8 | | | |
| Muscle Pain: Mild (N = 114) | 58.8 | | | |
| Muscle Pain: Moderate (N = 108) | 47.2 | | | |
| Muscle Pain: Severe (N = 89) | 10.1 | | | |
| Joint Pain: Any (N = 103) | 39.8 | | | |
| Joint Pain: Mild (N = 98) | 23.5 | | | |
| Joint Pain: Moderate (N = 94) | 23.4 | | | |
| Joint Pain: Severe (N = 89) | 4.5 | | | |
| Use of Antipyretic Medications (N = 110) | 58.2 | | | |

Notes:

[12] - Number of subjects analyzed signifies the safety population for Dose 1.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 2

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Prespecified Systemic Events: 13vPnC Dose 2 |
|-----------------|---|

End point description:

Specific systemic events (fever ≥ 38 degrees Celsius[C], vomiting, diarrhea, headache, fatigue, muscle pain, joint pain, use of antipyretic medications) were reported for each day using an electronic diary. Fatigue, headache, muscle pain and joint pain were scaled as: Any(symptom present); Mild(did not interfere with activity); Moderate(some interference); Severe(prevented routine daily activity). Vomiting was scaled as: Any(vomiting present); Mild(1-2 times in 24 hours); Moderate(>2 times in 24 hours); Severe(required intravenous hydration). Diarrhea was scaled as: Any(diarrhea present); Mild(2-3 loose stools in 24 hours); Moderate(4-5 loose stools 24 hours); Severe(≥ 6 loose stools in 24 hours). Safety population Dose 2- all subjects who received Dose 2 of study vaccine, had safety data available. "N" signifies those subjects who reported "Yes" for at least 1 day or "No" for for all days for specified local reaction. Subjects may be represented in more than 1 category.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Within 7 days after 13vPnC Dose 2

| End point values | 13vPnC | | | |
|---|---------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 140 ^[13] | | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever: ≥ 38 , ≤ 38.4 degrees C (N = 63) | 9.5 | | | |
| Fever: > 38.4 , ≤ 38.9 degrees C (N = 59) | 6.8 | | | |
| Fever: > 38.9 , ≤ 40 degrees C (N = 63) | 6.3 | | | |
| Fever: > 40 degrees C (N = 60) | 1.7 | | | |
| Vomiting: Any (N = 67) | 13.4 | | | |
| Vomiting: Mild (N = 65) | 9.2 | | | |
| Vomiting: Moderate (N = 64) | 4.7 | | | |
| Vomiting: Severe (N = 64) | 1.6 | | | |
| Diarrhea: Any (N = 68) | 25 | | | |
| Diarrhea: Mild (N = 68) | 19.1 | | | |
| Diarrhea: Moderate (N = 66) | 12.1 | | | |
| Diarrhea: Severe (N = 63) | 3.2 | | | |
| Headache: Any (N = 86) | 59.3 | | | |
| Headache: Mild (N = 74) | 41.9 | | | |
| Headache: Moderate (N = 76) | 36.8 | | | |
| Headache: Severe (N = 66) | 10.6 | | | |
| Fatigue: Any (N = 96) | 62.5 | | | |
| Fatigue: Mild (N = 84) | 48.8 | | | |
| Fatigue: Moderate (N = 83) | 41 | | | |
| Fatigue: Severe (N = 67) | 13.4 | | | |
| Muscle Pain: Any (N = 98) | 75.5 | | | |
| Muscle Pain: Mild (N = 87) | 60.9 | | | |
| Muscle Pain: Moderate (N = 84) | 45.2 | | | |
| Muscle Pain: Severe (N = 67) | 16.4 | | | |
| Joint Pain: Any (N = 78) | 44.9 | | | |
| Joint Pain: Mild (N = 72) | 34.7 | | | |
| Joint Pain: Moderate (N = 70) | 21.4 | | | |
| Joint Pain: Severe (N = 65) | 6.2 | | | |
| Use of Antipyretic Medications (N = 78) | 43.6 | | | |

Notes:

[13] - Number of subjects analyzed signifies the safety population for Dose 2.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs: Baseline up to 1 year after Dose 2. AEs: 1 month after each 13vPnC dose. Newly diagnosed chronic medical conditions: 6 months after each 13vPnC dose, at 1 year after 13vPnC Dose 2. Local reactions/systemic events: within 7 days after each dose

Adverse event reporting additional description:

Safety population: subjects who received at least 1 dose and had safety data available. AEs included events collected in electronic diary (systematic assessment for local reactions [LR] and systemic events [SE]) and events collected on case report form at each visit (non systematic assessment for SAEs and non-SAEs).

| | |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
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| | |
|--------------------|------|
| Dictionary version | 16.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | 13vPnC Dose 1 |
|-----------------------|---------------|

Reporting group description:

Subjects previously immunized with 23vPS who received a single 0.5 mL dose of 13vPnC intramuscular injection on Day 1 (13vPnC Dose 1), assessed between 13vPnC Dose 1 and before 13vPnC Dose2.

| | |
|-----------------------|---------------|
| Reporting group title | 13vPnC Dose 2 |
|-----------------------|---------------|

Reporting group description:

Subjects previously immunized with 23vPS who received Dose 2 of 0.5 mL 13vPnC intramuscular injection, assessed between 13vPnC Dose 2 and before 13vPnC Dose 2 blood draw.

| | |
|-----------------------|-------------------|
| Reporting group title | 6-Month Follow-up |
|-----------------------|-------------------|

Reporting group description:

Subjects previously immunized with 23vPS who received at least 1 of the 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart, assessed from last 13vPnC Dose (Dose 1 or Dose 2) blood draw to the 6-month follow-up telephone contact.

| | |
|-----------------------|------------------|
| Reporting group title | 1-Year Follow-up |
|-----------------------|------------------|

Reporting group description:

Subjects previously immunized with 23vPS who received 2 single 0.5 mL doses of 13vPnC intramuscular injection, 6 months apart, assessed from the 6-month follow-up telephone contact after 13vPnC Dose 2 to the 1-year follow-up after 13vPnC Dose 2.

| Serious adverse events | 13vPnC Dose 1 | 13vPnC Dose 2 | 6-Month Follow-up |
|---|-------------------|------------------|-------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 40 / 158 (25.32%) | 11 / 140 (7.86%) | 28 / 147 (19.05%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| Vascular disorders | | | |
| Vascular occlusion | | | |
| subjects affected / exposed | 3 / 158 (1.90%) | 2 / 140 (1.43%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pregnancy, puerperium and perinatal | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| conditions | | | |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 2 / 140 (1.43%) | 0 / 147 (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 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 5 / 158 (3.16%) | 0 / 140 (0.00%) | 2 / 147 (1.36%) |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 2 / 147 (1.36%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Chest pain | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| 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 | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Reproductive system and breast disorders | | | |
| Priapism | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute chest syndrome | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 3 / 158 (1.90%) | 0 / 140 (0.00%) | 2 / 147 (1.36%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lung infiltration | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| 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 failure | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |
| Mental status changes | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Injury, poisoning and procedural complications | | | |
| Overdose | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rib fracture | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Congenital, familial and genetic disorders | | | |
| Sickle cell anaemia with crisis | | | |

| | | | |
|---|-------------------|-----------------|-------------------|
| subjects affected / exposed | 22 / 158 (13.92%) | 5 / 140 (3.57%) | 17 / 147 (11.56%) |
| occurrences causally related to treatment / all | 0 / 30 | 0 / 6 | 0 / 25 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Cerebral infarction | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Headache | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Unresponsive to stimuli | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Lethargy | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Migraine | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Anaemia | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Haemolytic anaemia | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hypersplenism | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Visual impairment | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Gastritis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Gingivitis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Hiatus hernia | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Nausea | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Oesophagitis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Cholecystitis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Renal and urinary disorders | | | |
| Haematuria | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| 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 failure | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| 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 failure chronic | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Dysuria | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Back pain | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 1 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Flank pain | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Pain in extremity | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 2 / 140 (1.43%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pain in jaw | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Infections and infestations | | | |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 2 / 147 (1.36%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bone abscess | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Osteomyelitis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Groin abscess | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Hepatitis A | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Staphylococcal bacteraemia | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bacteraemia | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Device related infection | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Pharyngotonsillitis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Pyelonephritis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (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 |
| Metabolism and nutrition disorders | | | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|------------------|--|--|
| Serious adverse events | 1-Year Follow-up | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 16 / 87 (18.39%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |
| Vascular disorders | | | |
| Vascular occlusion | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Pregnancy | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 3 / 87 (3.45%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pain | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Priapism | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute chest syndrome | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Asthma | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|------------------|--|--|
| Lung infiltration | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory failure | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Mental status changes | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Overdose | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Rib fracture | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Congenital, familial and genetic disorders | | | |
| Sickle cell anaemia with crisis | | | |
| subjects affected / exposed | 11 / 87 (12.64%) | | |
| occurrences causally related to treatment / all | 0 / 17 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nervous system disorders | | | |
| Cerebrovascular accident | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cerebral infarction | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Headache | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypoaesthesia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Unresponsive to stimuli | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lethargy | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Migraine | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemolytic anaemia | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hypersplenism | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Eye disorders | | | |
| Visual impairment | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Constipation | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastritis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gingivitis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Nausea | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Oesophagitis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Cholecystitis acute | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cholecystitis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperbilirubinaemia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |
| Haematuria | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal failure | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal failure chronic | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dysuria | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Back pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Flank pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Muscular weakness | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pain in jaw | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |

| | | | | |
|---|----------------|--|--|--|
| Pneumonia | | | | |
| subjects affected / exposed | 4 / 87 (4.60%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bone abscess | | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bronchitis | | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis | | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Osteomyelitis | | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary tract infection | | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Groin abscess | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hepatitis A | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Sinusitis | | | | |

| | | | | |
|---|----------------|--|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Staphylococcal bacteraemia | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Upper respiratory tract infection | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Bacteraemia | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Device related infection | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pharyngitis | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pharyngotonsillitis | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyelonephritis | | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tonsillitis | | | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Hypocalcaemia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | 13vPnC Dose 1 | 13vPnC Dose 2 | 6-Month Follow-up |
|---|--------------------|--------------------|-------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 133 / 158 (84.18%) | 100 / 140 (71.43%) | 1 / 147 (0.68%) |
| Vascular disorders | | | |
| Vascular occlusion | | | |
| subjects affected / exposed | 4 / 158 (2.53%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |
| Hypertension | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 5 / 158 (3.16%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Chest pain | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Injection site pain | | | |

| | | | |
|---|------------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Asthenia | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site erythema | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injection site movement impairment | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Oedema peripheral | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Swelling | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 38.4^{\circ}\text{C}$ | | | |
| Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 11 / 81 (13.58%) | 6 / 63 (9.52%) | 0 / 147 (0.00%) |
| occurrences (all) | 11 | 6 | 0 |
| Fever $> 38.4^{\circ}\text{C}$ but $\leq 38.9^{\circ}\text{C}$ | | | |
| Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 6 / 82 (7.32%) | 4 / 59 (6.78%) | 0 / 147 (0.00%) |
| occurrences (all) | 6 | 4 | 0 |
| Fever $> 38.9^{\circ}\text{C}$ but $\leq 40.0^{\circ}\text{C}$ | | | |
| Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 3 / 79 (3.80%) | 4 / 63 (6.35%) | 0 / 147 (0.00%) |
| occurrences (all) | 3 | 4 | 0 |
| Fever $> 40.0^{\circ}\text{C}$ | | | |
| Additional description: Subjects affected and occurrences for SE is same as data | | | |

| | | | |
|--|---|------------------------|----------------------|
| collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all) | 1 / 79 (1.27%) 1 | 1 / 60 (1.67%) 1 | 0 / 147 (0.00%) 0 |
| Vomiting (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[5] occurrences (all) | 14 / 91 (15.38%) 14 | 9 / 67 (13.43%) 9 | 0 / 147 (0.00%) 0 |
| Vomiting (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[6] occurrences (all) | 10 / 89 (11.24%) 10 | 6 / 65 (9.23%) 6 | 0 / 147 (0.00%) 0 |
| Vomiting (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[7] occurrences (all) | 6 / 90 (6.67%) 6 | 3 / 64 (4.69%) 3 | 0 / 147 (0.00%) 0 |
| Vomiting (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[8] occurrences (all) | 0 / 87 (0.00%) 0 | 1 / 64 (1.56%) 1 | 0 / 147 (0.00%) 0 |
| Diarrhea (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[9] occurrences (all) | 12 / 90 (13.33%) 12 | 17 / 68 (25.00%) 17 | 0 / 147 (0.00%) 0 |
| Diarrhea (Mild) | Additional description: Subjects affected and occurrences for SE is same as data | | |

| | | | |
|---|---|------------------------|----------------------|
| collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[10] occurrences (all) | 6 / 87 (6.90%) 6 | 13 / 68 (19.12%) 13 | 0 / 147 (0.00%) 0 |
| Diarrhea (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[11] occurrences (all) | 6 / 90 (6.67%) 6 | 8 / 66 (12.12%) 8 | 0 / 147 (0.00%) 0 |
| Diarrhea (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[12] occurrences (all) | 2 / 87 (2.30%) 2 | 2 / 63 (3.17%) 2 | 0 / 147 (0.00%) 0 |
| Headache (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[13] occurrences (all) | 59 / 110 (53.64%) 59 | 51 / 86 (59.30%) 51 | 0 / 147 (0.00%) 0 |
| Headache (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[14] occurrences (all) | 45 / 105 (42.86%) 45 | 31 / 74 (41.89%) 31 | 0 / 147 (0.00%) 0 |
| Headache (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[15] occurrences (all) | 35 / 101 (34.65%) 35 | 28 / 76 (36.84%) 28 | 0 / 147 (0.00%) 0 |
| Headache (Severe) | Additional description: Subjects affected and occurrences for SE is same as data | | |

| | | | |
|---|---|------------------------|----------------------|
| collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[16] occurrences (all) | 11 / 92 (11.96%) 11 | 7 / 66 (10.61%) 7 | 0 / 147 (0.00%) 0 |
| Fatigue (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[17] occurrences (all) | 52 / 108 (48.15%) 52 | 41 / 84 (48.81%) 41 | 0 / 147 (0.00%) 0 |
| Fatigue (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[18] occurrences (all) | 46 / 104 (44.23%) 46 | 34 / 83 (40.96%) 34 | 0 / 147 (0.00%) 0 |
| Fatigue (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[19] occurrences (all) | 13 / 90 (14.44%) 13 | 9 / 67 (13.43%) 9 | 0 / 147 (0.00%) 0 |
| Muscle pain (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[20] occurrences (all) | 95 / 127 (74.80%) 95 | 74 / 98 (75.51%) 74 | 0 / 147 (0.00%) 0 |
| Muscle pain (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[21] occurrences (all) | 67 / 114 (58.77%) 67 | 53 / 87 (60.92%) 53 | 0 / 147 (0.00%) 0 |
| Muscle pain (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data | | |

| | | | |
|---|---|------------------------|----------------------|
| collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[22] occurrences (all) | 51 / 108 (47.22%) 51 | 38 / 84 (45.24%) 38 | 0 / 147 (0.00%) 0 |
| Muscle pain (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[23] occurrences (all) | 9 / 89 (10.11%) 9 | 11 / 67 (16.42%) 11 | 0 / 147 (0.00%) 0 |
| Joint pain (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[24] occurrences (all) | 41 / 103 (39.81%) 41 | 35 / 78 (44.87%) 35 | 0 / 147 (0.00%) 0 |
| Joint pain (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[25] occurrences (all) | 23 / 98 (23.47%) 23 | 25 / 72 (34.72%) 25 | 0 / 147 (0.00%) 0 |
| Joint pain (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[26] occurrences (all) | 22 / 94 (23.40%) 22 | 15 / 70 (21.43%) 15 | 0 / 147 (0.00%) 0 |
| Joint pain (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 alternative assessment type: Systematic subjects affected / exposed ^[27] occurrences (all) | 4 / 89 (4.49%) 4 | 4 / 65 (6.15%) 4 | 0 / 147 (0.00%) 0 |
| Respiratory, thoracic and mediastinal | | | |

| | | | |
|--|-----------------|-----------------|-----------------|
| disorders | | | |
| Rhinitis allergic | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 1 / 147 (0.68%) |
| occurrences (all) | 0 | 0 | 1 |
| Productive cough | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cough | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Epistaxis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Haemoptysis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nasal congestion | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |
| Listless | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Depression | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Insomnia | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|--|--|--|
| Transfusion reaction subjects affected / exposed occurrences (all) | 1 / 158 (0.63%) 1 | 0 / 140 (0.00%) 0 | 0 / 147 (0.00%) 0 |
| Congenital, familial and genetic disorders Sickle cell anaemia with crisis subjects affected / exposed occurrences (all) | 4 / 158 (2.53%) 4 | 1 / 140 (0.71%) 1 | 0 / 147 (0.00%) 0 |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) Convulsion subjects affected / exposed occurrences (all) Hypoaesthesia subjects affected / exposed occurrences (all) Moyamoya disease subjects affected / exposed occurrences (all) | 4 / 158 (2.53%) 4 1 / 158 (0.63%) 1 1 / 158 (0.63%) 1 1 / 158 (0.63%) 1 | 1 / 140 (0.71%) 1 0 / 140 (0.00%) 0 0 / 140 (0.00%) 0 0 / 140 (0.00%) 0 | 0 / 147 (0.00%) 0 0 / 147 (0.00%) 0 0 / 147 (0.00%) 0 0 / 147 (0.00%) 0 |
| Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all) | 0 / 158 (0.00%) 0 | 1 / 140 (0.71%) 1 | 0 / 147 (0.00%) 0 |
| Eye disorders Ocular icterus subjects affected / exposed occurrences (all) Periorbital oedema subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 158 (0.00%) 0 1 / 158 (0.63%) 1 1 / 158 (0.63%) 1 | 1 / 140 (0.71%) 1 1 / 140 (0.71%) 1 0 / 140 (0.00%) 0 | 0 / 147 (0.00%) 0 0 / 147 (0.00%) 0 0 / 147 (0.00%) 0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|--|------------------|-----------------|
| Hiatus hernia | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral pain | | | |
| subjects affected / exposed | 0 / 158 (0.00%) | 1 / 140 (0.71%) | 0 / 147 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Nausea | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pancreatic calcification | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fatigue (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[28] | 78 / 118 (66.10%) | 60 / 96 (62.50%) | 0 / 147 (0.00%) |
| occurrences (all) | 78 | 60 | 0 |

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|--|--|-------------------|-----------------|
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 2 / 158 (1.27%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Swelling face | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Pain (Any) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[29] | 129 / 144 (89.58%) | 95 / 111 (85.59%) | 0 / 147 (0.00%) |
| occurrences (all) | 129 | 95 | 0 |
| Pain (Mild) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[30] | 108 / 132 (81.82%) | 80 / 103 (77.67%) | 0 / 147 (0.00%) |
| occurrences (all) | 108 | 80 | 0 |
| Pain (Moderate) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[31] | 64 / 113 (56.64%) | 44 / 82 (53.66%) | 0 / 147 (0.00%) |
| occurrences (all) | 64 | 44 | 0 |
| Pain (Severe) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[32] | 10 / 90 (11.11%) | 11 / 69 (15.94%) | 0 / 147 (0.00%) |
| occurrences (all) | 10 | 11 | 0 |
| Redness (Any) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

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|--|---|------------------|-----------------|
| subjects affected / exposed ^[33] | 22 / 93 (23.66%) | 18 / 67 (26.87%) | 0 / 147 (0.00%) |
| occurrences (all) | 22 | 18 | 0 |
| Redness (Mild) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[34] | 19 / 93 (20.43%) | 10 / 66 (15.15%) | 0 / 147 (0.00%) |
| occurrences (all) | 19 | 10 | 0 |
| Redness (Moderate) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[35] | 8 / 90 (8.89%) | 9 / 64 (14.06%) | 0 / 147 (0.00%) |
| occurrences (all) | 8 | 9 | 0 |
| Redness (Severe) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[36] | 1 / 87 (1.15%) | 0 / 63 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Swelling (Any) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[37] | 53 / 108 (49.07%) | 45 / 84 (53.57%) | 0 / 147 (0.00%) |
| occurrences (all) | 53 | 45 | 0 |
| Swelling (Mild) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[38] | 38 / 101 (37.62%) | 29 / 77 (37.66%) | 0 / 147 (0.00%) |
| occurrences (all) | 38 | 29 | 0 |
| Swelling (Moderate) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

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|---|---|------------------------|----------------------|
| subjects affected / exposed ^[39] occurrences (all) | 26 / 100 (26.00%) 26 | 26 / 73 (35.62%) 26 | 0 / 147 (0.00%) 0 |
| Swelling (Severe) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 alternative assessment type: Systematic subjects affected / exposed ^[40] occurrences (all) | 1 / 87 (1.15%) 1 | 0 / 63 (0.00%) 0 | 0 / 147 (0.00%) 0 |
| Renal and urinary disorders Renal failure chronic subjects affected / exposed occurrences (all) | 1 / 158 (0.63%) 1 | 0 / 140 (0.00%) 0 | 0 / 147 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Pain in extremity subjects affected / exposed occurrences (all) | 2 / 158 (1.27%) 2 | 2 / 140 (1.43%) 3 | 0 / 147 (0.00%) 0 |
| Arthralgia subjects affected / exposed occurrences (all) | 0 / 158 (0.00%) 0 | 1 / 140 (0.71%) 1 | 0 / 147 (0.00%) 0 |
| Back pain subjects affected / exposed occurrences (all) | 1 / 158 (0.63%) 1 | 1 / 140 (0.71%) 1 | 0 / 147 (0.00%) 0 |
| Joint swelling subjects affected / exposed occurrences (all) | 0 / 158 (0.00%) 0 | 1 / 140 (0.71%) 1 | 0 / 147 (0.00%) 0 |
| Musculoskeletal chest pain subjects affected / exposed occurrences (all) | 1 / 158 (0.63%) 2 | 0 / 140 (0.00%) 0 | 0 / 147 (0.00%) 0 |
| Infections and infestations Pharyngitis subjects affected / exposed occurrences (all) | 1 / 158 (0.63%) 1 | 1 / 140 (0.71%) 1 | 0 / 147 (0.00%) 0 |
| Nasopharyngitis subjects affected / exposed occurrences (all) | 2 / 158 (1.27%) 2 | 0 / 140 (0.00%) 0 | 0 / 147 (0.00%) 0 |
| Infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 158 (0.63%) | 0 / 140 (0.00%) | 0 / 147 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

| | | | |
|---|------------------|--|--|
| Non-serious adverse events | 1-Year Follow-up | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| Vascular disorders | | | |
| Vascular occlusion | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| General disorders and administration site conditions | | | |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Chest pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Asthenia | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injection site erythema | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injection site movement impairment | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oedema peripheral | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Swelling | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 38.4^{\circ}\text{C}$ | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[1] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fever $> 38.4^{\circ}\text{C}$ but $\leq 38.9^{\circ}\text{C}$ | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[2] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fever $> 38.9^{\circ}\text{C}$ but $\leq 40.0^{\circ}\text{C}$ | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[3] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fever $> 40.0^{\circ}\text{C}$ | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |

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|---|---|--|--|
| subjects affected / exposed ^[4] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vomiting (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[5] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vomiting (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[6] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vomiting (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[7] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vomiting (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[8] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhea (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[9] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhea (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed ^[10] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhea (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[11] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhea (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[12] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Headache (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[13] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Headache (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[14] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Headache (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[15] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Headache (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed ^[16] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fatigue (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[17] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fatigue (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[18] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fatigue (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[19] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle pain (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[20] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle pain (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[21] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle pain (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|--|--|
| subjects affected / exposed ^[22] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Muscle pain (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[23] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint pain (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[24] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint pain (Mild) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[25] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint pain (Moderate) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[26] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Joint pain (Severe) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[27] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Rhinitis allergic | | | |

| | | | |
|--|----------------|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Productive cough | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Cough | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Haemoptysis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nasal congestion | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Psychiatric disorders | | | |
| Listless | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Depression | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Insomnia | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Injury, poisoning and procedural complications | | | |

| | | | |
|---|--|--|--|
| Transfusion reaction subjects affected / exposed occurrences (all) | 0 / 87 (0.00%) 0 | | |
| Congenital, familial and genetic disorders Sickle cell anaemia with crisis subjects affected / exposed occurrences (all) | 0 / 87 (0.00%) 0 | | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) Convulsion subjects affected / exposed occurrences (all) Hypoaesthesia subjects affected / exposed occurrences (all) Moyamoya disease subjects affected / exposed occurrences (all) | 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 | | |
| Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all) | 0 / 87 (0.00%) 0 | | |
| Eye disorders Ocular icterus subjects affected / exposed occurrences (all) Periorbital oedema subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all) | 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 0 / 87 (0.00%) 0 | | |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|--|--|
| Hiatus hernia | | | |
| subjects affected / exposed | 1 / 87 (1.15%) | | |
| occurrences (all) | 1 | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Gingival pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Oral pain | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Vomiting | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Constipation | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Nausea | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pancreatic calcification | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Fatigue (Any) | Additional description: Subjects affected and occurrences for SE is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[28] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |

| | | | |
|--|--|--|--|
| Hepatobiliary disorders | | | |
| Cholelithiasis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Swelling face | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain (Any) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[29] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain (Mild) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[30] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain (Moderate) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[31] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Pain (Severe) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[32] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Redness (Any) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaris cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|--|---|--|--|
| subjects affected / exposed ^[33] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Redness (Mild) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[34] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Redness (Moderate) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[35] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Redness (Severe) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[36] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Swelling (Any) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[37] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Swelling (Mild) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed ^[38] | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Swelling (Moderate) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|--|---|--|--|
| <p>subjects affected / exposed^[39]</p> <p>occurrences (all)</p> | <p>0 / 87 (0.00%)</p> <p>0</p> | | |
| Swelling (Severe) | Additional description: Subjects affected and occurrences for LR is same as data collected through ediaries cannot be used to distinguish one occurrence from another within a subject/vaccination. | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[40]</p> <p>occurrences (all)</p> | <p>0 / 87 (0.00%)</p> <p>0</p> | | |
| <p>Renal and urinary disorders</p> <p>Renal failure chronic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 87 (0.00%)</p> <p>0</p> | | |
| <p>Musculoskeletal and connective tissue disorders</p> <p>Pain in extremity</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Arthralgia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Back pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Joint swelling</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Musculoskeletal chest pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 87 (0.00%)</p> <p>0</p> <p>0 / 87 (0.00%)</p> <p>0</p> <p>0 / 87 (0.00%)</p> <p>0</p> <p>0 / 87 (0.00%)</p> <p>0</p> <p>0 / 87 (0.00%)</p> <p>0</p> | | |
| <p>Infections and infestations</p> <p>Pharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasopharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Infection</p> | <p>0 / 87 (0.00%)</p> <p>0</p> <p>0 / 87 (0.00%)</p> <p>0</p> | | |

| | | | |
|---|----------------|--|--|
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Rhinitis | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 87 (0.00%) | | |
| occurrences (all) | 0 | | |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[9] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[10] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[12] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

for all days.

[30] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[31] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[32] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[33] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[34] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[35] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[36] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[37] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[38] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[39] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[40] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported