



Clinical trial results:

Efficacy and Safety of a Novel Tetravalent Dengue Vaccine in Healthy Children and Adolescents Aged 9 to 16 Years in Latin America

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-001716-19 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 05 March 2018 |

Results information

| | |
|--------------------------------|--|
| Result version number | v3 (current) |
| This version publication date | 20 January 2023 |
| First version publication date | 02 August 2015 |
| Version creation reason | • Correction of full data set Updated safety optional field |

Trial information

Trial identification

| | |
|-----------------------|-------|
| Sponsor protocol code | CYD15 |
|-----------------------|-------|

Additional study identifiers

| | |
|------------------------------------|-----------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01374516 |
| WHO universal trial number (UTN) | U1111-1116-4986 |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Sanofi Pasteur |
| Sponsor organisation address | 14, Espace Henry Vallée, Lyon , France, 69007 |
| Public contact | Trial Transparency Team, Sanofi Pasteur , Contact-US@sanofi.com |
| Scientific contact | Trial Transparency Team, Sanofi Pasteur , Contact-US@sanofi.com |

Notes:

Paediatric regulatory details

| | |
|--|-----|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| 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 | 11 October 2018 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 05 March 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Efficacy of CYD dengue vaccine after 3 vaccinations (one each at 0, 6 and 12 months) in preventing symptomatic virologically-confirmed dengue cases, regardless of the severity, due to any of the four serotypes in children and adolescents aged 9 to 16 years at the time of inclusion.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were randomized and vaccinated in the study. Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment was also available on site in case of any immediate allergic reactions.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

| | |
|---|------------------|
| Actual start date of recruitment | 08 June 2011 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety, Efficacy |
| Long term follow-up duration | 72 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------------|
| Country: Number of subjects enrolled | Colombia: 9743 |
| Country: Number of subjects enrolled | Honduras: 2799 |
| Country: Number of subjects enrolled | Brazil: 3548 |
| Country: Number of subjects enrolled | Mexico: 3464 |
| Country: Number of subjects enrolled | Puerto Rico: 1315 |
| Worldwide total number of subjects | 20869 |
| EEA total number of subjects | 0 |

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) | 9458 |
| Adolescents (12-17 years) | 11411 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Study subjects were enrolled from 08 June 2011 to 16 March 2012 at 5 clinical centers in Brazil, 9 in Colombia, 1 in Honduras, 5 in Mexico, and 2 in Puerto Rico.

Pre-assignment

Screening details:

A total of 20869 subjects who met all of the inclusion and none of the exclusion criteria were enrolled and randomized in the study.

Period 1

| | |
|------------------------------|--|
| Period 1 title | Vaccination Phase (Up to 25 Months) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Assessor |

Blinding implementation details:

The observer-blind design was chosen since the products have different aspects and could be recognized. The person who performed vaccinations knew which product was administered while neither the subject nor the Investigator in charge of safety evaluation knew which product was injected. To maintain the blind and minimize any potential bias, the control group used the same route and schedule as the study vaccine.

Arms

| | |
|------------------------------|--------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | CYD Dengue vaccine group |

Arm description:

Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | CYD Dengue vaccine |
| Investigational medicinal product code | 323 |
| Other name | |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

| | |
|------------------|---------------|
| Arm title | Placebo group |
|------------------|---------------|

Arm description:

Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo (NaCl) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

| Number of subjects in period 1 | CYD Dengue vaccine group | Placebo group |
|--------------------------------|--------------------------|---------------|
| Started | 13920 | 6949 |
| Completed | 13281 | 6640 |
| Not completed | 639 | 309 |
| Consent withdrawn by subject | 480 | 240 |
| Adverse event, non-fatal | 3 | - |
| Serious adverse event | 7 | 9 |
| Lost to follow-up | 106 | 46 |
| Protocol deviation | 43 | 14 |

Period 2

| | |
|------------------------------|--|
| Period 2 title | Surveillance Expansion Period |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Assessor |

Arms

| | |
|------------------------------|--------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | CYD Dengue Vaccine Group |

Arm description:

Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | CYD Dengue vaccine |
| Investigational medicinal product code | 323 |
| Other name | |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

| | |
|------------------|---------------|
| Arm title | Placebo Group |
|------------------|---------------|

Arm description:

Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo (NaCl) |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

0.5 mL, subcutaneous, 3 injections. One each at 0, 6, and 12 months.

| Number of subjects in period 2 | CYD Dengue Vaccine Group | Placebo Group |
|---------------------------------------|--------------------------|---------------|
| Started | 13281 | 6640 |
| Completed | 10932 | 5387 |
| Not completed | 2349 | 1253 |
| Consent withdrawn by subject | 1870 | 986 |
| Serious adverse event | 20 | 5 |
| Lost to follow-up | 73 | 45 |
| Protocol deviation | 386 | 217 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | CYD Dengue vaccine group |
|-----------------------|--------------------------|

Reporting group description:

Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

| | |
|-----------------------|---------------|
| Reporting group title | Placebo group |
|-----------------------|---------------|

Reporting group description:

Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months).

| Reporting group values | CYD Dengue vaccine group | Placebo group | Total |
|--|--------------------------|---------------|-------|
| Number of subjects | 13920 | 6949 | 20869 |
| Age categorical Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 6307 | 3151 | 9458 |
| Adolescents (12-17 years) | 7613 | 3798 | 11411 |
| Adults (18-64 years) | 0 | 0 | 0 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Age continuous Units: years | | | |
| arithmetic mean | 12.5 | 12.5 | |
| standard deviation | ± 2.14 | ± 2.13 | - |
| Gender categorical Units: Subjects | | | |
| Female | 7048 | 3532 | 10580 |
| Male | 6872 | 3417 | 10289 |
| Region of Enrollment Units: Subjects | | | |
| Colombia | 6497 | 3246 | 9743 |
| Brazil | 2370 | 1178 | 3548 |
| Mexico | 2312 | 1152 | 3464 |
| Honduras | 1866 | 933 | 2799 |
| Puerto Rico | 875 | 440 | 1315 |

End points

End points reporting groups

| | |
|---|--------------------------|
| Reporting group title | CYD Dengue vaccine group |
| Reporting group description: Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months). | |
| Reporting group title | Placebo group |
| Reporting group description: Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months). | |
| Reporting group title | CYD Dengue Vaccine Group |
| Reporting group description: Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months). | |
| Reporting group title | Placebo Group |
| Reporting group description: Subjects received 3 doses of placebo matched to vaccine; one each at 0, 6, and 12 months and were followed up to 60 months after last vaccination (or a total duration of up to 72 months). | |

Primary: Number of Symptomatic Virologically Confirmed Dengue (VCD) Cases Due to Any Serotype During the Active Phase Post-dose 3 Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|--|--|
| End point title | Number of Symptomatic Virologically Confirmed Dengue (VCD) Cases Due to Any Serotype During the Active Phase Post-dose 3 Following Injection With Either CYD Dengue Vaccine or a Placebo |
| End point description: Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature $\geq 38^{\circ}\text{C}$ on at least 2 consecutive days) and confirmation of dengue virus infection by dengue reverse transcriptase polymerase chain reaction (RT-PCR) and/or dengue non-structural (NS) protein 1 antigen enzyme-linked immunosorbent assay (ELISA). Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Per-Protocol Analysis Set for Efficacy, defined as subjects who had no protocol deviations. | |
| End point type | Primary |
| End point timeframe: 28 days and up to 13 months post-injection 3 | |

| End point values | CYD Dengue vaccine group | Placebo group | | |
|-----------------------------|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12574 | 6261 | | |
| Units: Cases | | | | |
| number (not applicable) | 176 | 221 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Vaccine efficacy of the CYD dengue vaccine |
| Statistical analysis description: | |
| The statistical methodology was based on the use of the two-sided 95 percent (%) confidence interval (CI) of the vaccine efficacy (expressed in %). The CI was calculated using the exact method conditional on the total number of cases in both groups (exact method by Breslow & Day). The vaccine efficacy of the CYD dengue vaccine was considered significant if the lower bound of its 95% CI was greater than 25%. | |
| Comparison groups | CYD Dengue vaccine group v Placebo group |
| Number of subjects included in analysis | 18835 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Vaccine Efficacy |
| Point estimate | 60.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 52 |
| upper limit | 68 |

Secondary: Number of Symptomatic VCD Cases Due to Any Serotype During the Active Phase Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|--|---|
| End point title | Number of Symptomatic VCD Cases Due to Any Serotype During the Active Phase Following Injection With Either CYD Dengue Vaccine or a Placebo |
| End point description: | |
| Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature $\geq 38^{\circ}\text{C}$ on at least 2 consecutive days) and confirmation of dengue virus infection by dengue RT-PCR and/or dengue NS 1 ELISA. Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Full Analysis Set for Efficacy, which included all subjects who received at least 1 injection. | |
| End point type | Secondary |
| End point timeframe: | |
| Day 0 up to 13 months post-injection 3 | |

| | | | | |
|-----------------------------|--------------------------|-----------------|--|--|
| End point values | CYD Dengue vaccine group | Placebo group | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13914 | 6940 | | |
| Units: Cases | | | | |
| number (not applicable) | 277 | 385 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Vaccine efficacy of the CYD dengue vaccine |
| Statistical analysis description: | |
| The statistical methodology was based on the use of the two-sided 95% confidence interval (CI) of the | |

vaccine efficacy (expressed in %). The CI was calculated using the exact method conditional on the total number of cases in both groups (exact method by Breslow & Day). The vaccine efficacy of the CYD dengue vaccine was considered significant if the lower bound of its 95% CI was greater than 25%.

| | |
|---|--|
| Comparison groups | CYD Dengue vaccine group v Placebo group |
| Number of subjects included in analysis | 20854 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Vaccine Efficacy |
| Point estimate | 64.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 58.7 |
| upper limit | 69.8 |

Secondary: Number of Symptomatic VCD Cases Due to Any Serotype Occurring 28 Days Post-dose 1 Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|------------------------|--|
| End point title | Number of Symptomatic VCD Cases Due to Any Serotype Occurring 28 Days Post-dose 1 Following Injection With Either CYD Dengue Vaccine or a Placebo |
| End point description: | Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature $\geq 38^{\circ}\text{C}$ on at least 2 consecutive days) and confirmation of dengue virus infection by dengue RT-PCR and/or dengue NS 1 ELISA. Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Full Analysis Set for Efficacy, which included subjects who received at least 1 dose of study vaccine. |
| End point type | Secondary |
| End point timeframe: | 28 days post-injection 1 and up to 13 months post-injection 3 |

| End point values | CYD Dengue vaccine group | Placebo group | | |
|-----------------------------|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13914 | 6940 | | |
| Units: Cases | | | | |
| number (not applicable) | 273 | 380 | | |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Vaccine efficacy of CYD dengue vaccine |
| Statistical analysis description: | The statistical methodology was based on the use of the two-sided 95% CI of the vaccine efficacy (expressed in %) calculated using the exact method conditional on the total number of cases in both groups. |
| Comparison groups | CYD Dengue vaccine group v Placebo group |

| | |
|---|------------------|
| Number of subjects included in analysis | 20854 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Vaccine Efficacy |
| Point estimate | 64.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 58.7 |
| upper limit | 69.9 |

Secondary: Number of Symptomatic VCD Cases Due to Any Serotype Post-dose 2 Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|------------------------|--|
| End point title | Number of Symptomatic VCD Cases Due to Any Serotype Post-dose 2 Following Injection With Either CYD Dengue Vaccine or a Placebo |
| End point description: | Symptomatic VCD cases were defined as occurrence of acute febrile illness (temperature $\geq 38^{\circ}\text{C}$ on at least 2 consecutive days) and confirmation of dengue virus infection by dengue RT-PCR and/or dengue NS 1 ELISA. Vaccine efficacy was defined as 1 minus the ratio of density incidence due to any serotype after at least 1 dose in the CYD Dengue Vaccine Group over the density incidence of the Placebo Group. Number of symptomatic VCD cases were assessed in the Other Efficacy Analysis Set, which included subjects who received at least 2 doses of study vaccine. |
| End point type | Secondary |
| End point timeframe: | 28 days post-injection 2 and up to 13 months post-injection 3 |

| End point values | CYD Dengue vaccine group | Placebo group | | |
|-----------------------------|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13506 | 6765 | | |
| Units: Cases | | | | |
| number (not applicable) | 236 | 306 | | |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Vaccine efficacy of the CYD dengue vaccine |
| Statistical analysis description: | The statistical methodology was based on the use of the two-sided 95% CI of the vaccine efficacy (expressed in %) calculated using the exact method conditional on the total number of cases in both groups. |
| Comparison groups | CYD Dengue vaccine group v Placebo group |

| | |
|---|------------------|
| Number of subjects included in analysis | 20271 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Vaccine Efficacy |
| Point estimate | 61.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 54.7 |
| upper limit | 68 |

Secondary: Number of Symptomatic VCD Cases Meeting World Health Organization (WHO) Criteria Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|-----------------|---|
| End point title | Number of Symptomatic VCD Cases Meeting World Health Organization (WHO) Criteria Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo |
|-----------------|---|

End point description:

Dengue hemorrhagic fever (DHF) cases were defined as number of subjects with at least one symptomatic VCD episode meeting the 1997 WHO criteria (a)Fever: acute onset, high ($\geq 38^{\circ}\text{C}$) and continuous, lasting 2 to 7days and (b)any of the pre-listed hemorrhagic manifestations and laboratory findings of thrombocytopenia (platelet $\leq 100 \times 10^9/\text{L}$) and plasma leakage as shown by hemoconcentration (hematocrit increased by 20% or more) or pleural effusion (seen on Chest X-Ray [CXR]) and/or ascites and/ or hypoalbuminemia. DHF was graded as follows: Grade I: Fever accompanied by non-specific constitutional symptoms; Grade II: Spontaneous bleeding in addition to the manifestations of Grade I subjects, usually in the form of skin and/or other hemorrhage. Number of WHO dengue hemorrhagic fever cases were assessed in the Safety Analysis Set, which included all subjects who received at least one dose of study vaccine. Here, 'subjects analysed' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 0 to the end of study (up to 72 months)

| End point values | CYD Dengue vaccine group | Placebo group | | |
|--|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12809 | 6380 | | |
| Units: Cases | | | | |
| number (not applicable) | | | | |
| Due to Any of the 4 Serotypes: Any Grade | 7 | 15 | | |
| Due to Any of the 4 Serotypes: Grade I | 0 | 2 | | |
| Due to Any of the 4 Serotypes: Grade II | 7 | 13 | | |
| Due to Any of the 4 Serotypes: Grade III | 0 | 0 | | |
| Due to Any of the 4 Serotypes: Grade IV | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Symptomatic VCD Cases Meeting WHO Criteria During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|-----------------|---|
| End point title | Number of Symptomatic VCD Cases Meeting WHO Criteria During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo |
|-----------------|---|

End point description:

The 1997 WHO criteria: a)Fever: acute onset, high ($\geq 38^{\circ}\text{C}$) and continuous, for 2 to 7days and (b)any of the following: thrombocytopenia (platelet $\leq 100 \times 10^9/\text{L}$) and plasma leakage as shown by hematocrit increased by 20% or more or pleural effusion and/or ascites and/or hypoalbuminemia. DHF was graded as follows: Grade I:Fever accompanied by non-specific constitutional symptoms; Grade II:Spontaneous bleeding in addition to the manifestations of Grade I subject, usually in the form of skin and/or other hemorrhages; Grade III:Circulatory failure manifested by rapid and weak pulse, narrowing of pulse pressure (20mmHg or less) or hypotension, with the presence of cold clammy skin and restlessness; and Grade IV: Profound shock with undetectable blood pressure and pulse. Number of WHO DHF cases were assessed in the Full Analysis Set for Surveillance Expansion Period, which included all subjects who received at least 1 injection and accepted to be included in the Surveillance Expansion Period.

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

End point timeframe:

From consent to participate in the Surveillance Expansion Period to the end of study (up to 72 months)

| End point values | CYD Dengue Vaccine Group | Placebo Group | | |
|--|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11063 | 5430 | | |
| Units: Cases | | | | |
| number (not applicable) | | | | |
| Due to Any of the 4 Serotypes: Any Grade | 2 | 0 | | |
| Due to Any of the 4 Serotypes: Grade I | 0 | 0 | | |
| Due to Any of the 4 Serotypes: Grade II | 2 | 0 | | |
| Due to Any of the 4 Serotypes: Grade III | 0 | 0 | | |
| Due to Any of the 4 Serotypes: Grade IV | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Hospitalized VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|-----------------|---|
| End point title | Number of Hospitalized VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo |
|-----------------|---|

End point description:

Hospitalized VCD cases were defined as VCD confirmed by dengue RT-PCR and/or dengue NS 1 ELISA in subjects with acute febrile illness (temperature $\geq 38^{\circ}\text{C}$ on at least 2 consecutive days) requiring hospitalization. Number of hospitalized dengue hemorrhagic fever cases were assessed in the Safety Analysis Set. Here, 'subjects analysed' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 0 up to the end of study (up to 72 months)

| End point values | CYD Dengue vaccine group | Placebo group | | |
|-----------------------------|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12809 | 6380 | | |
| Units: Cases | | | | |
| number (not applicable) | 46 | 71 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Hospitalized VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|-----------------|---|
| End point title | Number of Hospitalized VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo |
|-----------------|---|

End point description:

Hospitalized VCD cases were defined as VCD confirmed by dengue RT-PCR and/or dengue NS 1 ELISA in subjects with acute febrile illness (temperature $\geq 38^{\circ}\text{C}$ on at least 2 consecutive days) requiring hospitalization. Analysis was performed in the Safety Analysis Set.

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

End point timeframe:

From consent to participate in the Surveillance Expansion Period to the end of study (up to 72 months)

| End point values | CYD Dengue vaccine group | Placebo group | | |
|-----------------------------|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 13915 | 6939 | | |
| Units: Cases | | | | |
| number (not applicable) | 5 | 2 | | |

Statistical analyses

Secondary: Number of Clinically Severe VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|-----------------|--|
| End point title | Number of Clinically Severe VCD Cases Throughout the Trial Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo |
|-----------------|--|

End point description:

The Severity of VCD cases was assessed by an Independent Data monitoring Committee (IDMC) based on medical review of cases and any of following criteria: 1) Platelet count $\leq 100000/\mu\text{L}$ and bleeding (tourniquet, petechiae or any bleeding) plus plasma leakage 2) Shock (pulse pressure $\leq 20\text{mmHg}$ in child, or hypotension [$\leq 90\text{mmHg}$] with tachycardia, weak pulse and poor perfusion) 3) Bleeding requiring blood transfusion 4) Encephalopathy i.e. unconsciousness or poor conscious state. Poor conscious state or unconsciousness must be supported by Glasgow Coma Scale (GCS) score 5) Liver impairment (AST $>1000\text{IU/L}$ or prothrombin time [PT] International normalized ratio [INR] >1.5) excluding other causes of viral hepatitis 6) Impaired kidney function (serum creatinine $\geq 1.5\text{mg/dL}$) 7) Myocarditis, pericarditis or clinical heart failure supported by CXR, echocardiography, ECG or cardiac enzymes. Analysis was performed in Safety Analysis Set. Here, 'subjects analysed' = subjects evaluable for this endpoint.

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

End point timeframe:

Day 0 to the end of study (up to 72 months)

| End point values | CYD Dengue vaccine group | Placebo group | | |
|-----------------------------|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 12809 | 6380 | | |
| Units: Cases | | | | |
| number (not applicable) | 9 | 16 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Clinically Severe VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|-----------------|--|
| End point title | Number of Clinically Severe VCD Cases During the Surveillance Expansion Period Due to Any Serotype Following Injection With Either CYD Dengue Vaccine or a Placebo |
|-----------------|--|

End point description:

The severity of VCD cases was assessed by an IDMC based on a medical review of cases and any of the following criteria: -1) Platelet count $\leq 100000/\mu\text{L}$ and bleeding (tourniquet, petechiae or any bleeding) plus plasma leakage 2) Shock (pulse pressure $\leq 20\text{mmHg}$ in a child, or hypotension [$\leq 90\text{mmHg}$] with tachycardia, weak pulse and poor perfusion) 3) Bleeding requiring blood transfusion 4) Encephalopathy i.e. Unconsciousness or poor conscious state or fitting not attributable to simple febrile convulsion or focal neurological signs. Poor conscious state or unconsciousness must be supported by GCS score 5) Liver impairment (AST $>1000\text{IU/L}$ or PT INR >1.5) excluding other causes of viral hepatitis 6) Impaired kidney function (serum creatinine $\geq 1.5\text{mg/dL}$) 7) Myocarditis, pericarditis or clinical heart failure supported by CXR, echocardiography, ECG or cardiac enzymes. Number of clinically severe VCD cases were assessed in the Full Analysis Set for Surveillance Expansion Period.

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

End point timeframe:

From consent to participate in the Surveillance Expansion Period to the end of study (up to 72 months)

| End point values | CYD Dengue vaccine group | Placebo group | | |
|-----------------------------|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 11061 | 5431 | | |
| Units: Cases | | | | |
| number (not applicable) | 42 | 34 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Antibody Titers ≥ 10 1/Dil Against Each Dengue Virus Serotype Before and Following Injection (Inj.) With CYD Dengue Vaccine or Placebo

| | |
|-----------------|---|
| End point title | Percentage of Subjects With Antibody Titers ≥ 10 1/Dil Against Each Dengue Virus Serotype Before and Following Injection (Inj.) With CYD Dengue Vaccine or Placebo |
|-----------------|---|

End point description:

Dengue neutralizing antibody levels against each of the 4 dengue virus serotypes (parental strains) were measured by the plaque reduction neutralization test (PRNT) in a pre-defined subset of subjects. Antibody titers against each dengue virus serotype strain were assessed in Full Analysis Set for Immunogenicity (FASI), which included a subset of subjects who received at least one dose of vaccine and had a blood sample drawn and result available after the dose. Here, 'n' = subjects with available data for each specified category.

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

End point timeframe:

Pre-injection 1, 28 days post Injections 2 and 3, 13 months and 60 months post-injection 3

| End point values | CYD Dengue vaccine group | Placebo group | | |
|--|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1301 | 643 | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Dengue virus Serotype 1: Pre-Inj.1 (n=1297,641) | 72.8 | 70.5 | | |
| Dengue virus Serotype 1: Post-Inj. 2 (n=1296,638) | 92.7 | 71.8 | | |
| Dengue virus Serotype 1: Post-Inj. 3 (n=1291,640) | 94.9 | 74.2 | | |
| Dengue virus Serotype 1;1yr Post-Inj.3(n=1261,629) | 85.6 | 73.6 | | |
| Dengue virus Serotype 1;5yr Post-Inj.3(n=1038,508) | 90.0 | 81.1 | | |

| | | | | |
|--|------|------|--|--|
| Dengue virus Serotype 2; Pre-Inj. 1 (n=1299,640) | 76.1 | 73.8 | | |
| Dengue virus Serotype 2; Post-Inj. 2 (n=1297,639) | 97.5 | 75.1 | | |
| Dengue virus Serotype 2; Post-Inj. 3 (n=1291,640) | 98.5 | 77.2 | | |
| Dengue virus Serotype 2; 1yr Post-Inj. 3(n=1264,629) | 94.1 | 78.9 | | |
| Dengue virus Serotype 2; 5yr Post-Inj. 3(n=1038,508) | 93.5 | 83.1 | | |
| Dengue virus Serotype 3; Pre-Inj. 1 (n=1300,639) | 76.5 | 73.6 | | |
| Dengue virus Serotype 3; Post-Inj. 2 (n=1297,639) | 98.5 | 75.7 | | |
| Dengue virus Serotype 3; Post-Inj. 3 (n=1291,640) | 98.4 | 78.0 | | |
| Dengue virus Serotype 3; 1yr Post-Inj. 3(n=1265,629) | 92.7 | 76.2 | | |
| Dengue virus Serotype 3; 5yr Post-Inj. 3(n=1038,508) | 95.4 | 82.7 | | |
| Dengue virus Serotype 4; Pre-Inj. 1 (n=1297,640) | 68.2 | 65.0 | | |
| Dengue virus Serotype 4; Post-Inj. 2 (n=1295,637) | 96.9 | 67.0 | | |
| Dengue virus Serotype 4; Post-Inj. 3 (n=1291,640) | 98.1 | 68.9 | | |
| Dengue virus Serotype 4; 1yr Post-Inj. 3(n=1265,625) | 94.9 | 69.0 | | |
| Dengue virus Serotype 4; 5yr Post-Inj. 3(n=1038,508) | 96.3 | 78.9 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Each Dengue Virus Serotype Before and Following Injection With Either CYD Dengue Tetravalent Vaccine or a Placebo

| | |
|-----------------|---|
| End point title | Geometric Mean Titers of Antibodies Against Each Dengue Virus Serotype Before and Following Injection With Either CYD Dengue Tetravalent Vaccine or a Placebo |
|-----------------|---|

End point description:

Geometric mean titers for each of the 4 dengue virus serotypes (parental strains) were assessed using the plaque reduction neutralization test (PRNT) in a pre-defined subset of subjects. Antibody titers against each dengue virus serotype strain were assessed in FASI, which included a subset of subjects who received at least one dose of vaccine and had a blood sample drawn and result available after the dose. Here, 'n' = subjects with available data for each specified category.

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

End point timeframe:

Pre-injection 1, 28 days post Injections 2 and 3, 13 months and 60 months post-injection 3

| End point values | CYD Dengue vaccine group | Placebo group | | |
|--|--------------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1301 | 643 | | |
| Units: Titers (1/dilution) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Dengue virus Serotype 1: Pre-Inj. 1 (n=1297,641) | 128 (112 to 145) | 119 (98.7 to 142) | | |
| Dengue virus Serotype 1: Post-Inj. 2 (n=1296,638) | 458 (406 to 517) | 128 (106 to 154) | | |
| Dengue virus Serotype 1: Post-Inj. 3 (n=1291,640) | 395 (353 to 441) | 121 (101 to 145) | | |
| Dengue virus Serotype 1;1yr Post-Inj.3(n=1261,629) | 266 (234 to 302) | 146 (121 to 176) | | |
| Dengue virus Serotype 1;5yr Post-Inj.3(n=1038,508) | 284 (252 to 321) | 210 (172 to 255) | | |
| Dengue virus Serotype 2; Pre-Inj. 1 (n=1299,640) | 138 (123 to 156) | 115 (97.2 to 136) | | |
| Dengue virus Serotype 2; Post-Inj. 2 (n=1297,639) | 622 (566 to 684) | 124 (104 to 148) | | |
| Dengue virus Serotype 2; Post-Inj. 3 (n=1291,640) | 574 (528 to 624) | 129 (109 to 152) | | |
| Dengue virus Serotype 2;1yr Post-Inj.3(n=1264,629) | 371 (336 to 409) | 145 (122 to 173) | | |
| Dengue virus Serotype 2;5yr Post-Inj.3(n=1038,508) | 297 (269 to 328) | 201 (168 to 242) | | |
| Dengue virus Serotype 3; Pre-Inj. 1 (n=1300,639) | 121 (108 to 136) | 114 (95.9 to 136) | | |
| Dengue virus Serotype 3; Post-Inj. 2 (n=1297,639) | 556 (506 to 610) | 117 (98.3 to 139) | | |
| Dengue virus Serotype 3; Post-Inj. 3 (n=1291,640) | 508 (465 to 555) | 124 (105 to 147) | | |
| Dengue virus Serotype 3;1yr Post-Inj.3(n=1265,629) | 292 (263 to 325) | 137 (114 to 165) | | |
| Dengue virus Serotype 3;5yr Post-Inj.3(n=1038,508) | 346 (313 to 383) | 224 (185 to 271) | | |
| Dengue virus Serotype 4; Pre-Inj. 1(n=1297,640) | 43.6 (39.6 to 48.0) | 39.0 (33.9 to 44.7) | | |
| Dengue virus Serotype 4; Post-Inj. 2 (n=1295,637) | 261 (242 to 281) | 40.9 (35.5 to 47.0) | | |
| Dengue virus Serotype 4; Post-Inj. 3 (n=1291,640) | 241 (226 to 258) | 44.3 (38.6 to 50.8) | | |
| Dengue virus Serotype 4;1yr Post-Inj.3(n=1265,625) | 174 (161 to 188) | 51.5 (44.3 to 59.8) | | |
| Dengue virus Serotype 4;5yr Post-Inj.3(n=1038,508) | 144 (134 to 156) | 73.6 (63.4 to 85.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Injection Site Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|-----------------|---|
| End point title | Number of Subjects With Solicited Injection Site Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo |
|-----------------|---|

End point description:

Solicited injection site reactions: Pain, Erythema, and Swelling. Grade 3 reactions (9-11 years): Pain: incapacitating, unable to perform usual activities; Erythema and Swelling, ≥ 50 mm. Grade 3 Solicited injection site reactions (12-16 years): Pain: significant, prevents daily activity; Erythema and Swelling, >100 mm. Solicited injection site reactions were assessed in a subset of the Safety Analysis Set, which included all subjects who received at least one dose of study vaccine and who were evaluated for reactogenicity. Here, 'number analyzed' = subjects with available data for specified category.

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

End point timeframe:

Within 7 days after each and any injection

| End point values | CYD Dengue vaccine group | Placebo group | | |
|--|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1333 | 664 | | |
| Units: Subjects | | | | |
| number (not applicable) | | | | |
| Injection-site Pain (Post any inj.) (n=1328,658) | 650 | 270 | | |
| Injection-site Erythema(Post-any inj.)(n=1328,658) | 83 | 44 | | |
| Injection-site Swelling(Post-any inj.)(n=1328,658) | 77 | 27 | | |
| Injection-site Pain (Post-inj. 1)(n=1326,657) | 430 | 173 | | |
| Grade 3 Inj.-site Pain (Post-inj.1)(n=1326,657) | 11 | 6 | | |
| Injection-site Erythema (Post-inj.1)(n=1326,656) | 55 | 31 | | |
| Grade3 Inj.-site Erythema (Post-inj.1)(n=1326,656) | 0 | 1 | | |
| Injection-site Swelling (Post-inj. 1)(n=1326,656) | 47 | 18 | | |
| Grade3 Inj.-site Swelling (Post-inj.1)(n=1326,656) | 0 | 1 | | |
| Injection-site Pain (Post-inj. 2)(n=1297,639) | 332 | 105 | | |
| Grade3 Injection-site Pain(Post-inj.2)(n=1297,639) | 7 | 0 | | |
| Injection-site Erythema (Post-inj.2) (n=1296,639) | 25 | 11 | | |
| Grade3 Inj.-site Erythema (Post-inj.2)(n=1296,639) | 1 | 0 | | |
| Injection-site Swelling (Post-inj. 2)(n=1296,639) | 25 | 6 | | |
| Grade3 Inj.-site Swelling (Post-inj.2)(n=1296,639) | 0 | 0 | | |
| Injection-site Pain (Post-inj. 3)(n=1279,630) | 288 | 104 | | |
| Grade 3 Inj-site Pain (Post-inj. 3)(n=1279,630) | 11 | 2 | | |
| Injection-site Erythema (Post-inj. 3)(n=1278,631) | 19 | 10 | | |
| Grade3 Inj.-site Erythema (Post-inj.3)(n=1278,631) | 0 | 0 | | |
| Injection-site Swelling (Post-inj. 3) (n=1279,631) | 20 | 8 | | |

| | | | | |
|---|---|---|--|--|
| Grade3 Inj.-site Swelling (Postinj.3) (n=1279,631) | 0 | 0 | | |
|---|---|---|--|--|

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Solicited Systemic Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo

| | |
|------------------------|---|
| End point title | Number of Subjects With Solicited Systemic Reactions Following Any and Each Injection With Either CYD Dengue Vaccine or a Placebo |
| End point description: | Solicited systemic reactions: Fever (Temperature), Headache, Malaise, Myalgia, and Asthenia. Grade 3 reactions: Fever: $\geq 39^{\circ}\text{C}$; Headache, Malaise, Myalgia, and Asthenia: significant, prevents daily activity. Solicited systemic reactions were assessed in a subset of the Safety Analysis Set, which included all subjects who received at least one dose of study vaccine and who were evaluated for reactogenicity. Here, 'n' = subjects with available data for specified category. |
| End point type | Secondary |
| End point timeframe: | Within 14 days after each and any injection |

| End point values | CYD Dengue vaccine group | Placebo group | | |
|--|--------------------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 1333 | 664 | | |
| Units: Subjects | | | | |
| number (not applicable) | | | | |
| Fever (Post any inj.) (n=1318,654) | 220 | 123 | | |
| Headache (Post any inj.) (n=1328,659) | 727 | 379 | | |
| Malaise (Post any inj.) (n=1328,659) | 536 | 261 | | |
| Myalgia (Post any inj.) (n=1328,659) | 576 | 267 | | |
| Asthenia (Post any inj.) (n=1328,659) | 496 | 251 | | |
| Fever (Post-inj. 1) (n=1264,635) | 86 | 42 | | |
| Grade 3 Fever (Post-inj. 1) (n=1264,635) | 21 | 7 | | |
| Headache (Post-inj. 1) (n=1324,657) | 528 | 273 | | |
| Grade 3 Headache (Post-inj. 1) (n=1324,657) | 67 | 27 | | |
| Malaise (Post-inj. 1) (n=1323,657) | 324 | 170 | | |
| Grade 3 Malaise (Post-inj. 1) (n=1323,657) | 32 | 15 | | |
| Myalgia (Post-inj. 1) (n=1323,657) | 386 | 180 | | |
| Grade 3 Myalgia (Post-inj. 1) (n=1323,657) | 29 | 10 | | |
| Asthenia (Post-inj. 1) (n=1323,657) | 326 | 148 | | |
| Grade 3 Asthenia (Post-inj. 1) (n=1323,657) | 36 | 17 | | |
| Fever (Post-inj. 2) (n=1228,594) | 72 | 42 | | |

| | | | | |
|--|-----|-----|--|--|
| Grade 3 Fever (Post-inj. 2) (n=1228,594) | 10 | 7 | | |
| Headache (Post-inj. 2) (n=1297,639) | 386 | 182 | | |
| Grade 3 Headache (Post-inj. 2) (n=1297,639) | 27 | 15 | | |
| Malaise (Post-inj. 2) (n=1298,639) | 270 | 106 | | |
| Grade 3 Malaise (Post-inj. 2) (n=1298,639) | 17 | 8 | | |
| Myalgia (Post-inj. 2) (n=1298,639) | 273 | 101 | | |
| Grade 3 Myalgia (Post-inj. 2) (n=1298,639) | 21 | 5 | | |
| Asthenia (Post-inj. 2) (n=1298,639) | 231 | 105 | | |
| Grade 3 Asthenia (Post-inj. 2) (n=1298,639) | 24 | 7 | | |
| Fever (Post-inj. 3) (n=1215,597) | 89 | 52 | | |
| Grade 3 Fever (Post-inj. 3) (n=1215,597) | 13 | 5 | | |
| Headache (Post-inj. 3) (n=1277,631) | 378 | 158 | | |
| Grade 3 Headache (Post-inj. 3) (n=1277,631) | 33 | 12 | | |
| Malaise (Post-inj. 3) (n=1277,631) | 246 | 96 | | |
| Grade 3 Malaise (Post-inj. 3) (n=1277,631) | 18 | 7 | | |
| Myalgia (Post-inj. 3) (n=1277,631) | 255 | 116 | | |
| Grade 3 Myalgia (Post-inj. 3) (n=1277,631) | 19 | 5 | | |
| Asthenia (Post-inj. 3) (n=1277,631) | 208 | 110 | | |
| Grade 3 Asthenia (Post-inj. 3) (n=1277,631) | 17 | 8 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Unsolicited adverse event (AE) data: collected from Day 0 (post-vaccination) up to 28 days after each vaccination. Solicited Reaction (SR) data: within 7 and 14 days after vaccination. Serious adverse event (SAE) data was collected throughout the study.

Adverse event reporting additional description:

Safety Analysis Set. A SR was an AE that was prelisted (i.e., solicited) in the electronic case report form (eCRF) and considered to be related to vaccination (adverse drug reaction). An unsolicited AE was an observed AE that did not fulfill the conditions prelisted (i.e., solicited) in the eCRF in terms of symptom and/or onset post-vaccination.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 14.0 |

Reporting groups

| | |
|-----------------------|--------------------------|
| Reporting group title | CYD Dengue Vaccine Group |
|-----------------------|--------------------------|

Reporting group description:

Subjects received 3 doses of CYD dengue vaccine; one each at 0, 6, and 12 months.

| | |
|-----------------------|---------------|
| Reporting group title | Placebo Group |
|-----------------------|---------------|

Reporting group description:

subjects received 3 doses of placebo vaccine; one each at 0, 6, and 12 months.

| Serious adverse events | CYD Dengue Vaccine Group | Placebo Group | |
|---|--------------------------|------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1765 / 13915 (12.68%) | 911 / 6939 (13.13%) | |
| number of deaths (all causes) | 42 | 27 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Benign Hydatidiform Mole | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign Ovarian Tumour | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Benign Pancreatic Neoplasm | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone Giant Cell Tumour | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bone Sarcoma | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Brain Neoplasm Malignant | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondrosarcoma | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chronic Myeloid Leukaemia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Desmoid Tumour | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibroadenoma Of Breast | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemangioma Of Skin | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hodgkin's Disease | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leukaemia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteochondroma | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteoma | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteosarcoma Metastatic | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Osteosarcoma Recurrent | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Ovarian Adenoma | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian Germ Cell Teratoma Benign | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pituitary Tumour Benign | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thyroid Cancer | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine Leiomyoma | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Hypertensive Crisis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Secondary Hypertension | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Abortion Induced | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Induced Complete | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Caesarean Section | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystectomy | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obesity Surgery | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scoliosis Surgery | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgery | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical Hernia Repair | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abnormal Product Of Conception | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion | | | |
| subjects affected / exposed | 14 / 13915 (0.10%) | 6 / 6939 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Complete | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 9 / 13915 (0.06%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Complicated | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Incomplete | | | |
| subjects affected / exposed | 22 / 13915 (0.16%) | 9 / 6939 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 22 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Incomplete Complicated | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Missed | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Of Ectopic Pregnancy | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Spontaneous | | | |
| subjects affected / exposed | 48 / 13915 (0.34%) | 30 / 6939 (0.43%) | |
| occurrences causally related to treatment / all | 0 / 51 | 0 / 34 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Spontaneous Complete | | | |
| subjects affected / exposed | 8 / 13915 (0.06%) | 6 / 6939 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Spontaneous Complicated | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Spontaneous Incomplete | | | |
| subjects affected / exposed | 16 / 13915 (0.11%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Spontaneous Incomplete Complicated | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Threatened | | | |
| subjects affected / exposed | 14 / 13915 (0.10%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amniorrhexis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Antepartum Haemorrhage | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blighted Ovum | | | |
| subjects affected / exposed | 11 / 13915 (0.08%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cephalo-Pelvic Disproportion | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cervical Incompetence | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complication Of Delivery | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Delivery | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eclampsia | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ectopic Pregnancy | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Failed Induction Of Labour | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| False Labour | | | |
| subjects affected / exposed | 39 / 13915 (0.28%) | 14 / 6939 (0.20%) | |
| occurrences causally related to treatment / all | 0 / 45 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foetal Distress Syndrome | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gestational Hypertension | | | |

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|---|--------------------|------------------|--|
| subjects affected / exposed | 12 / 13915 (0.09%) | 7 / 6939 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| HELLP Syndrome | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| High Risk Pregnancy | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperemesis Gravidarum | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intra-Uterine Death | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intrapartum Haemorrhage | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oligohydramnios | | | |
| subjects affected / exposed | 12 / 13915 (0.09%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Placental Insufficiency | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postpartum Haemorrhage | | | |

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|---|--------------------|-------------------|--|
| subjects affected / exposed | 8 / 13915 (0.06%) | 5 / 6939 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pre-Eclampsia | | | |
| subjects affected / exposed | 34 / 13915 (0.24%) | 23 / 6939 (0.33%) | |
| occurrences causally related to treatment / all | 0 / 35 | 0 / 23 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Premature Baby | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Premature Delivery | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Premature Labour | | | |
| subjects affected / exposed | 17 / 13915 (0.12%) | 6 / 6939 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Premature Rupture Of Membranes | | | |
| subjects affected / exposed | 13 / 13915 (0.09%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Premature Separation Of Placenta | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Prolonged Labour | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Puerperal Pyrexia | | | |

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|--|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retained Placenta Or Membranes | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retained Products Of Conception | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ruptured Ectopic Pregnancy | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stillbirth | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 5 / 6939 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Threatened Labour | | | |
| subjects affected / exposed | 7 / 13915 (0.05%) | 9 / 6939 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Catheter Site Phlebitis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cyst | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Death | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Device Intolerance | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Discomfort | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drowning | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 2 | |
| Malaise | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medical Device Complication | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia | | | |
| subjects affected / exposed | 9 / 13915 (0.06%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft Tissue Inflammation | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sudden Death | | | |

| | | | |
|--|-------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Immune system disorders | | | |
| Allergy To Arthropod Sting | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic Reaction | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anti-Neutrophil Cytoplasmic Antibody Positive Vasculitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Antiphospholipid Syndrome | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug Hypersensitivity | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food Allergy | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Social circumstances | | | |
| Physical Assault | | | |
| subjects affected / exposed | 9 / 13915 (0.06%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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| Sexual Abuse | | | |
| subjects affected / exposed | 7 / 13915 (0.05%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Substance Use | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Victim Of Crime | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Victim Of Homicide | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 1 | |
| Victim Of Sexual Abuse | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Adenomyosis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Balanitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bartholinitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|-------------------|------------------|--|
| Breast Disorder | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Mass | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Pain | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Coital Bleeding | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysfunctional Uterine Bleeding | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometriosis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epididymitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Female Genital Tract Fistula | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gynaecomastia | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematocolpos | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematosalpinx | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic Ovarian Cyst | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metrorrhagia | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian Cyst | | | |
| subjects affected / exposed | 7 / 13915 (0.05%) | 5 / 6939 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian Cyst Ruptured | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian Torsion | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovulation Pain | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic Pain | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polycystic Ovaries | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retrograde Menstruation | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular Disorder | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular Torsion | | | |
| subjects affected / exposed | 12 / 13915 (0.09%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine Cyst | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine Haemorrhage | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal Haemorrhage | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicocele | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval Haematoma | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute Pulmonary Oedema | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Acute Respiratory Failure | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Adenoidal Hypertrophy | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alveolitis Allergic | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asphyxia | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Aspiration | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Asthma | | | |
| subjects affected / exposed | 19 / 13915 (0.14%) | 17 / 6939 (0.24%) | |
| occurrences causally related to treatment / all | 1 / 24 | 0 / 22 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asthmatic Crisis | | | |
| subjects affected / exposed | 12 / 13915 (0.09%) | 7 / 6939 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 14 | 0 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchial Obstruction | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epistaxis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemothorax | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal Septum Deviation | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasal Turbinate Hypertrophy | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oropharyngeal Pain | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleurisy | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Artery Stenosis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Oedema | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Respiratory Tract Haemorrhage | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status Asthmaticus | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillar Cyst | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillar Hypertrophy | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Abnormal Behaviour | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Psychosis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Stress Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adjustment Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aggression | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anorexia Nervosa | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anxiety Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar I Disorder | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bipolar Disorder | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Completed Suicide | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 2 | |
| Conduct Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Conversion Disorder | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dependence | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 18 / 13915 (0.13%) | 9 / 6939 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression Suicidal | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dissociative Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug Abuse | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Drug Dependence | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional Drug Misuse | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional Self-Injury | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intermittent Explosive Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Major Depression | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 6 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Obsessive Rumination | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychotic Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizophrenia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizophrenia, Undifferentiated Type | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Somatoform Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Substance Abuse | | | |
| subjects affected / exposed | 14 / 13915 (0.10%) | 9 / 6939 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicidal Ideation | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suicide Attempt | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 19 / 13915 (0.14%) | 8 / 6939 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 19 | 0 / 14 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Autoimmune Hepatitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bile Duct Stone | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis | | | |
| subjects affected / exposed | 7 / 13915 (0.05%) | 6 / 6939 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis Acute | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystitis Chronic | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis | | | |
| subjects affected / exposed | 9 / 13915 (0.06%) | 13 / 6939 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 9 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholestasis Of Pregnancy | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gallbladder Disorder | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis Acute | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis Toxic | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocholecystitis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Investigation | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Abdominal Injury | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-------------------|------------------|--|
| Accident | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accident At Home | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Accident At Work | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acetabulum Fracture | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adverse Event Following Immunisation | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Alcohol Poisoning | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Animal Bite | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ankle Fracture | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropod Sting | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Avulsion Fracture | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns Second Degree | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Burns Third Degree | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chemical Poisoning | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest Injury | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Clavicle Fracture | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endotracheal Intubation Complication | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiphyseal Fracture | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye Injury | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye Penetration | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Face Injury | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Facial Bones Fracture | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fall | | | |
| subjects affected / exposed | 28 / 13915 (0.20%) | 11 / 6939 (0.16%) | |
| occurrences causally related to treatment / all | 0 / 28 | 0 / 12 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Femur Fracture | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibula Fracture | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foot Fracture | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Forearm Fracture | | | |
| subjects affected / exposed | 21 / 13915 (0.15%) | 7 / 6939 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 21 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign Body | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign Body In Eye | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genital Injury | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gun Shot Wound | | | |
| subjects affected / exposed | 24 / 13915 (0.17%) | 15 / 6939 (0.22%) | |
| occurrences causally related to treatment / all | 0 / 24 | 0 / 15 | |
| deaths causally related to treatment / all | 0 / 12 | 0 / 9 | |
| Hand Fracture | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Head Injury | | | |
| subjects affected / exposed | 16 / 13915 (0.11%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 17 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Humerus Fracture | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 6 / 13915 (0.04%) | 5 / 6939 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intentional Overdose | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint Dislocation | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint Injury | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb Crushing Injury | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb Injury | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb Traumatic Amputation | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower Limb Fracture | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 3 / 13915 (0.02%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lumbar Vertebral Fracture | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus Lesion | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple Fractures | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Multiple Injuries | | | |
| subjects affected / exposed | 12 / 13915 (0.09%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 2 | 0 / 0 | |
| Muscle Injury | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nerve Injury | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Open Wound | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perineal Laceration | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumothorax Traumatic | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Poisoning | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Poisoning Deliberate | | | |
| subjects affected / exposed | 15 / 13915 (0.11%) | 10 / 6939 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 16 | 0 / 10 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Post Procedural Haemorrhage | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-Traumatic Pain | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative Wound Complication | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural Complication | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Radius Fracture | | | |

| | | | |
|---|---------------------|-------------------|--|
| subjects affected / exposed | 8 / 13915 (0.06%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road Traffic Accident | | | |
| subjects affected / exposed | 108 / 13915 (0.78%) | 39 / 6939 (0.56%) | |
| occurrences causally related to treatment / all | 0 / 109 | 0 / 39 | |
| deaths causally related to treatment / all | 0 / 5 | 0 / 5 | |
| Skull Fracture | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft Tissue Injury | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal Cord Injury | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Spinal Cord Injury Cervical | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Sports Injury | | | |
| subjects affected / exposed | 8 / 13915 (0.06%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stab Wound | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon Injury | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tendon Rupture | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Testicular Injury | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thermal Burn | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia Fracture | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxicity To Various Agents | | | |
| subjects affected / exposed | 7 / 13915 (0.05%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Traumatic Brain Injury | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Traumatic Fracture | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulna Fracture | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 3 / 13915 (0.02%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulnar Nerve Injury | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper Limb Fracture | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular Access Complication | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wrist Fracture | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Arteriovenous Malformation | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atrial Septal Defect | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cryptorchism | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hereditary Spherocytosis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Phimosis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sickle Cell Trait | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Tachycardia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wolff-Parkinson-White Syndrome | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Acute Disseminated Encephalomyelitis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Polyneuropathy | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|--------------------|-------------------|--|
| Arachnoid Cyst | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Atonic Seizures | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebellar Syndrome | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Complicated Migraine | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Convulsion | | | |
| subjects affected / exposed | 21 / 13915 (0.15%) | 10 / 6939 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 31 | 0 / 11 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dizziness | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Encephalitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Epilepsy | | | |
| subjects affected / exposed | 26 / 13915 (0.19%) | 8 / 6939 (0.12%) | |
| occurrences causally related to treatment / all | 0 / 86 | 0 / 27 | |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | |
| Grand Mal Convulsion | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Guillain-Barre Syndrome | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage Intracranial | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Haemorrhagic Cerebral Infarction | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hydrocephalus | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersomnia | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertensive Encephalopathy | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Idiopathic Generalised Epilepsy | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intracranial Aneurysm | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine With Aura | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine Without Aura | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neuropathy Peripheral | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Partial Seizures | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-Traumatic Headache | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status Epilepticus | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Status Migrainosus | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syncope | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viith Nerve Paralysis | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia Of Pregnancy | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Aplastic Anaemia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhagic Anaemia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Idiopathic Thrombocytopenic Purpura | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Iron Deficiency Anaemia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenitis | | | |
| subjects affected / exposed | 7 / 13915 (0.05%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphoid Tissue Hyperplasia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombocytopenic Purpura | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Tympanic Membrane Perforation | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo | | | |

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|---|--------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Keratoconus | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal Detachment | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual Impairment | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal Adhesions | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal Pain | | | |
| subjects affected / exposed | 26 / 13915 (0.19%) | 9 / 6939 (0.13%) | |
| occurrences causally related to treatment / all | 0 / 26 | 0 / 9 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal Pain Lower | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal Pain Upper | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Abdomen | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal Haemorrhage | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Constipation | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enteritis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Faecaloma | | | |

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|---|--------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Food Poisoning | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis | | | |
| subjects affected / exposed | 12 / 13915 (0.09%) | 5 / 6939 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis Haemorrhagic | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gingivitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal Hernia | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inguinal Hernia, Obstructive | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal Functional Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal Obstruction | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intussusception | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Irritable Bowel Syndrome | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malocclusion | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis Acute | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peptic Ulcer | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stomatitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical Hernia | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical Hernia, Obstructive | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varices Oesophageal | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting In Pregnancy | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dermatitis Atopic | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erythema | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erythema Nodosum | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Henoch-Schonlein Purpura | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertrophic Scar | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mechanical Urticaria | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash Erythematous | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin Fissures | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous Nodule | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urticaria | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Calculus Ureteric | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus Urethral | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Calculus Urinary | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cystitis Haemorrhagic | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Glomerulonephritis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria | | | |

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|---|--------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lupus Nephritis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Nephritic Syndrome | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrolithiasis | | | |
| subjects affected / exposed | 15 / 13915 (0.11%) | 5 / 6939 (0.07%) | |
| occurrences causally related to treatment / all | 0 / 15 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post Streptococcal Glomerulonephritis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Colic | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Failure | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal Tubular Necrosis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tubulointerstitial Nephritis | | | |

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|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urogenital Haemorrhage | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Basedow's Disease | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypothalamo-Pituitary Disorder | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Ankle Deformity | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthropathy | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Back Pain | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epiphysiolysis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|-------------------|------------------|--|
| Intervertebral Disc Protrusion | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Juvenile Arthritis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Knee Deformity | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myopathy | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myositis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pathological Fracture | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rhabdomyolysis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatic Fever | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rheumatoid Arthritis | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sacroiliitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovial Cyst | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Systemic Lupus Erythematosus | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal Abscess | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abortion Infected | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess Limb | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess Neck | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess Of Salivary Gland | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abscess Oral | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Sinusitis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Acute Tonsillitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Adenoiditis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amniotic Cavity Infection | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amoebiasis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amoebic Dysentery | | | |

| | | | |
|---|---------------------|--------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal Abscess | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anogenital Warts | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis | | | |
| subjects affected / exposed | 261 / 13915 (1.88%) | 138 / 6939 (1.99%) | |
| occurrences causally related to treatment / all | 0 / 261 | 0 / 138 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendicitis Perforated | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis Bacterial | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Arthritis Infective | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Asymptomatic Hiv Infection | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bacterial Infection | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bartholin's Abscess | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Abscess | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast Cellulitis | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchiolitis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchitis | | | |
| subjects affected / exposed | 8 / 13915 (0.06%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bronchopneumonia | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Carbuncle | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cellulitis | | | |

| | | |
|---|---------------------|-------------------|
| subjects affected / exposed | 50 / 13915 (0.36%) | 35 / 6939 (0.50%) |
| occurrences causally related to treatment / all | 0 / 50 | 0 / 35 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Chikungunya Virus Infection | | |
| subjects affected / exposed | 8 / 13915 (0.06%) | 3 / 6939 (0.04%) |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Chorioamnionitis | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Chronic Sinusitis | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Chronic Tonsillitis | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 2 / 6939 (0.03%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cutaneous Anthrax | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Cystitis | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Dengue Fever | | |
| subjects affected / exposed | 101 / 13915 (0.73%) | 94 / 6939 (1.35%) |
| occurrences causally related to treatment / all | 0 / 104 | 0 / 94 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 |
| Endometritis | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometritis Decidual | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Enterocolitis Infectious | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Erysipelas | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| External Ear Cellulitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye Infection Toxoplasmal | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Flavivirus Infection | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis | | | |
| subjects affected / exposed | 34 / 13915 (0.24%) | 21 / 6939 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 34 | 0 / 21 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Bacterial | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastroenteritis Viral | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal Bacterial Infection | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal Infection | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal Viral Infection | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genital Infection Female | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genitourinary Tract Infection | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Granuloma Inguinale | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| H1n1 Influenza | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiv Infection | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hiv Infection Cdc Category A3 | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Helminthic Infection | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis A | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatitis Viral | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes Zoster | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Herpes Zoster Ophthalmic | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected Bites | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infectious Mononucleosis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infective Myositis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Influenza | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Leptospirosis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lower Respiratory Tract Infection | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung Infection | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaria | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastitis | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 4 / 13915 (0.03%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastitis Postpartum | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mastoiditis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis Bacterial | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meningitis Viral | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mononucleosis Syndrome | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mumps | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Mycoplasma Infection | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nasopharyngitis | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Orchitis | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Osteomyelitis Chronic | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis Media | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis Media Chronic | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis Mumps | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Panencephalitis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | |
| Parasitic Gastroenteritis | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic Inflammatory Disease | | | |
| subjects affected / exposed | 10 / 13915 (0.07%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perineal Abscess | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perineal Infection | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Periorbital Cellulitis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonsillar Abscess | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pharyngotonsillitis | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pilonidal Cyst | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia | | | |

| | | | |
|---|--------------------|-------------------|--|
| subjects affected / exposed | 18 / 13915 (0.13%) | 13 / 6939 (0.19%) | |
| occurrences causally related to treatment / all | 0 / 18 | 0 / 13 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia Bacterial | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia Mycoplasmal | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post Procedural Infection | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative Wound Infection | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 4 / 6939 (0.06%) | |
| occurrences causally related to treatment / all | 0 / 8 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postpartum Sepsis | | | |
| subjects affected / exposed | 4 / 13915 (0.03%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary Tuberculosis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis | | | |
| subjects affected / exposed | 10 / 13915 (0.07%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 12 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis Acute | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 7 / 13915 (0.05%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retroperitoneal Abscess | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salmonellosis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scarlet Fever | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Secondary Syphilis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin Infection | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Soft Tissue Infection | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 13 / 13915 (0.09%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 13 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Syphilis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis Bacterial | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tooth Abscess | | | |
| subjects affected / exposed | 6 / 13915 (0.04%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Toxoplasmosis | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tracheitis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tuberculosis | | | |

| | | | |
|---|---------------------|-------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Typhoid Fever | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 3 / 6939 (0.04%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 118 / 13915 (0.85%) | 59 / 6939 (0.85%) | |
| occurrences causally related to treatment / all | 0 / 127 | 0 / 69 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary Tract Infection Bacterial | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urosepsis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vaginal Infection | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Varicella | | | |
| subjects affected / exposed | 3 / 13915 (0.02%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral Cardiomyopathy | | | |

| | | | |
|---|--------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral Infection | | | |
| subjects affected / exposed | 10 / 13915 (0.07%) | 7 / 6939 (0.10%) | |
| occurrences causally related to treatment / all | 0 / 10 | 0 / 7 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visceral Leishmaniasis | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulval Abscess | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound Infection | | | |
| subjects affected / exposed | 5 / 13915 (0.04%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 5 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetes Mellitus Inadequate Control | | | |
| subjects affected / exposed | 0 / 13915 (0.00%) | 2 / 6939 (0.03%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diabetic Ketoacidosis | | | |
| subjects affected / exposed | 2 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia | | | |

| | | | |
|---|-------------------|------------------|--|
| subjects affected / exposed | 1 / 13915 (0.01%) | 0 / 6939 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Type 1 Diabetes Mellitus | | | |
| subjects affected / exposed | 1 / 13915 (0.01%) | 1 / 6939 (0.01%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events | CYD Dengue Vaccine Group | Placebo Group | |
|---|--------------------------|--------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1038 / 13915 (7.46%) | 515 / 6939 (7.42%) | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed ^[1] | 753 / 1333 (56.49%) | 388 / 664 (58.43%) | |
| occurrences (all) | 1385 | 652 | |
| General disorders and administration site conditions | | | |
| Asthenia | | | |
| subjects affected / exposed ^[2] | 500 / 1333 (37.51%) | 253 / 664 (38.10%) | |
| occurrences (all) | 771 | 366 | |
| Injection Site Erythema | | | |
| subjects affected / exposed ^[3] | 83 / 1333 (6.23%) | 44 / 664 (6.63%) | |
| occurrences (all) | 99 | 52 | |
| Injection Site Pain | | | |
| subjects affected / exposed ^[4] | 650 / 1333 (48.76%) | 270 / 664 (40.66%) | |
| occurrences (all) | 1056 | 384 | |
| Injection Site Swelling | | | |
| subjects affected / exposed ^[5] | 77 / 1333 (5.78%) | 27 / 664 (4.07%) | |
| occurrences (all) | 92 | 32 | |
| Malaise | | | |
| subjects affected / exposed ^[6] | 539 / 1333 (40.44%) | 264 / 664 (39.76%) | |
| occurrences (all) | 853 | 383 | |
| Pyrexia | | | |

| | | | |
|---|------------------------|--------------------|--|
| subjects affected / exposed ^[7] | 238 / 1333 (17.85%) | 127 / 664 (19.13%) | |
| occurrences (all) | 270 | 142 | |
| Musculoskeletal and connective tissue disorders | | | |
| Myalgia | | | |
| subjects affected / exposed ^[8] | 578 / 1333 (43.36%) | 267 / 664 (40.21%) | |
| occurrences (all) | 921 | 400 | |
| Infections and infestations | | | |
| Influenza | | | |
| subjects affected / exposed ^[9] | 76 / 1333 (5.70%) | 37 / 664 (5.57%) | |
| occurrences (all) | 80 | 40 | |
| Nasopharyngitis | | | |
| subjects affected / exposed ^[10] | 150 / 1333 (11.25%) | 60 / 664 (9.04%) | |
| occurrences (all) | 163 | 70 | |

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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in accordance with the protocol.

[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: Non-serious adverse events were assessed in a subset of subjects in each group, in

accordance with the protocol.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|---|
| 21 January 2011 | Major modifications included Venezuela declined its participation, clarified efficacy during the Active Phase, end of febrile episode was further clarified, frequency of contact during the Hospital Phase was increased to 1 every 3 months, potential manifestations of severity were updated, clarified that the safety surveillance was conducted by the Principal Investigators, transaminases were available to add in the assessment of the severity of confirmed dengue cases, clarification on the reporting of SAEs during the Active Phase and the Hospital Phase, and clarification on subjects who discontinued from vaccination or trial and their continuation in the study for surveillance purposes. |
| 03 August 2011 | Clarified collection periods of acute and convalescent samples, SAE reporting period was extended throughout the entire study, clarified that laboratory staff was blinded to treatment allocation, age stratification was clarified (9 to 11 years and 12 to 16 years), updated time window of assessment of serious viscerotropic disease, and introduced the use of the WHO Verbal Autopsy Questionnaire. |
| 29 May 2013 | Modified the testing algorithm for the virological-confirmation of dengue cases to maximize the likelihood of detecting dengue cases, updated and clarified text of secondary objectives as it relates to the assessment of the CYD dengue vaccine in preventing symptomatic virologically-confirmed cases, Hospital Phase was extended by 2 years to allow a 5 year follow-up period after the last vaccination, "Other Objectives" section was added, and included re-consenting of subjects for the 2-year extension and for additional testing to identify the dengue virus. |
| 25 January 2015 | An enhanced surveillance system (the SEP) following 1 year or more of the Hospital Phase was implemented, the trial's objectives and endpoints were updated to be consistent with additional study goals, the management of suspected dengue cases was modified. |
| 20 June 2016 | Section 5.1.1 "Trial Design" was updated to add the anti Zika antibody detection, the detection of Zika infection in febrile episodes occurring from start of 2013 (retrospectively) until the end of the trial, in order to differentiate Zika cases from Dengue cases; and the Zika virus sequencing on Zika infection positive samples, three objectives were added in Section 2.3. "Other Objectives", the definition of clinically severe dengue cases was clarified, endpoints corresponding to the 3 additional objectives were added, in Section 5.1.4, the use of the blood samples for anti-Zika antibody response evaluation was added, in Section 12.1.3. "Statistical Methods for other objectives" a new subsection (Relationship between Dengue and Zika) was added. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported