Clinical trial results:
Phase III, Double-Blind, Randomized, Placebo-Controlled Trial to Investigate the Efficacy, Safety and Immunogenicity of a Tetravalent Dengue Vaccine (TDV) Administered Subcutaneously in Healthy Children Aged 4 - 16 Years Old

Summary

EudraCT number	2018-003979-34
Trial protocol	Outside EU/EEA
Global end of trial date	28 June 2024

Results information

Result version number	v3 (current)
This version publication date	05 February 2026
First version publication date	12 March 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	DEN-301

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02747927
WHO universal trial number (UTN)	U1111-1166-8401
Other trial identifiers	PHRR: PHRR150522-001010

Notes:

Sponsors

Sponsor organisation name	Takeda Vaccines, Inc.
Sponsor organisation address	40 Landsdowne Street, Cambridge, MA, United States, 02139
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001888-PIP01-15
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	28 June 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 June 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the efficacy of 2 doses of Tetravalent Dengue Vaccine (TDV) in preventing symptomatic dengue fever of any severity and due to any of the four dengue virus serotypes in 4 to 16 year old participants. In addition, the efficacy of a TDV booster dose was assessed.

Protection of trial subjects:

All study participants or their parents/guardians/legally authorised representatives were required to read and sign an informed consent form. Assent was also obtained from the participant where required.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 April 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Brazil: 1774
Country: Number of subjects enrolled	Colombia: 3900
Country: Number of subjects enrolled	Dominican Republic: 1600
Country: Number of subjects enrolled	Nicaragua: 825
Country: Number of subjects enrolled	Panama: 3000
Country: Number of subjects enrolled	Philippines: 3927
Country: Number of subjects enrolled	Sri Lanka: 2100
Country: Number of subjects enrolled	Thailand: 2973
Worldwide total number of subjects	20099
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	13661
Adolescents (12-17 years)	6438
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at various investigative sites globally from 26 April 2016 to 28 June 2024.

Pre-assignment

Screening details:

Healthy children and adolescents were randomized in a 2:1 ratio to receive either tetravalent dengue vaccine (TDV) or placebo followed by a booster vaccination. 20067 participants were part of Safety Set [consisted of all randomized participants who received at least 1 dose of trial vaccines (TDV or placebo)].

Pre-assignment period milestones

Number of subjects started	20099
Number of subjects completed	20067

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Received At least 1 Incorrect Dose of TrialVaccine: 4
Reason: Number of subjects	Did Not Receive Even 1 Dose of Trial Vaccine: 28

Period 1

Period 1 title	Part 1: Vaccine Efficacy (Months 0-15)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching, 0.5 mL, SC injection.

Arm title	TDV 0.5 mL

Arm description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental

Investigational medicinal product name	Tetravalent Dengue Vaccine (TDV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for dispersion for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 mL SC injection.

Number of subjects in period 1[1]	Placebo	TDV 0.5 mL
Started	6687	13380
Completed	6519	13033
Not completed	168	347
Adverse event, non-fatal	5	14
Pregnancy	19	42
Without Adult Consent in Place	1	4
Lost to follow-up	13	26
Withdrawal by Participantand/orParent/Guardian	122	245
Reason not Specified	6	13
Protocol deviation	2	3

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The Baseline was collected for Safety Set which included all randomized participants who received at least 1 dose of the trial vaccines (TDV or placebo).

Period 2

Period 2 title	Part 2: Additional VE (Months 16-21)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching, 0.5 ml, SC injection

Arm title	TDV 0.5 mL

Arm description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Tetravalent Dengue Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for dispersion for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 ml, SC injection

Number of subjects in period 2	Placebo	TDV 0.5 mL
Started	6519	13033
Completed	6487	12961
Not completed	32	72
Adverse event, non-fatal	-	1
Pregnancy	11	17
Without Adult Consent in Place	1	7
Lost to follow-up	4	8
Withdrawal by Participant&/or theirParent/Guardian	13	33
Reason not Specified	3	6

Period 3

Period 3 title	Part 3: Long Term Safety & VE (3 Years)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	No

Arm title	Placebo

Arm description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching, 0.5 ml, SC injection

Arm title	TDV 0.5 mL

Arm description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Tetravalent Dengue Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for dispersion for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 ml, SC injection

Number of subjects in period 3	Placebo	TDV 0.5 mL
Started	6487	12961
Completed	6079	12177
Not completed	408	784
Adverse event, non-fatal	6	10
Pregnancy	120	228
Without Adult Consent in Place	82	150
Lost to follow-up	67	149
Withdrawal by Participant&/or theirParent/Guardian	119	227
Reason not Specified	13	18
Protocol deviation	1	2

Period 4

Period 4 title	Part 4: Booster VE & Safety (13 Months)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching, 0.5 ml, SC injection

Arm title	TDV 0.5 mL

Arm description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Tetravalent Dengue Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for dispersion for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV, 0.5 ml, SC injection

Number of subjects in period 4	Placebo	TDV 0.5 mL
Started	2985	5990
Completed	2939	5889
Not completed	46	101
Adverse event, non-fatal	1	3
Pregnancy	8	15
Without Adult Consent in Place	-	1
Lost to follow-up	4	13
Withdrawal by Participant&/or theirParent/Guardian	29	60
Reason not Specified	4	9

Period 5

Period 5 title	Part 5: Booster VE & Safety (1 Year)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV placebo-matching, 0.5 ml, SC injection.

Arm title	TDV 0.5 mL

Arm description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Arm type	Experimental
Investigational medicinal product name	Tetravalent Dengue Vaccine (TDV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for dispersion for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

TDV 0.5 ml SC injection.

Number of subjects in period 5	Placebo	TDV 0.5 mL
Started	2939	5889
Completed	2841	5671
Not completed	98	218
Consent withdrawn by subject	18	40
Adverse event, non-fatal	-	3
Pregnancy	18	27
Without Adult Consent in Place	14	29
Lost to follow-up	8	30
Reason not Specified	40	89

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.	
Reporting group title	TDV 0.5 mL
Reporting group description:	
Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.	

Reporting group values	Placebo	TDV 0.5 mL	Total
Number of subjects	6687	13380	20067
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	9.6	9.6	
standard deviation	± 3.34	± 3.36	-
Gender categorical Units: Subjects			
Male	3411	6729	10140
Female	3276	6651	9927
Race Units: Subjects			
American Indian or Alaska Native	2622	5236	7858
Asian	2985	5988	8973
Black or African American	760	1453	2213
Native Hawaiian or Other Pacific Islander	1	2	3
White	149	329	478
More than one race or Unknown	170	372	542
Height			
' n' indicates number analyzed is number of participants with data available for height at baseline			
Units: cm			
arithmetic mean	134.87	134.84	
standard deviation	± 18.976	± 19.151	-
Weight			
'n' indicates number analyzed is number of participants with data available for weight at baseline.			
Units: kg			
arithmetic mean	33.77	33.98	
standard deviation	± 14.506	± 14.951	-
Body Mass Index (BMI)			
BMI=weight (kg)/[height (m)^2] 'n' indicates number analyzed is number of participants with data available for BMI at baseline.			
Units: kg/m^2			

arithmetic mean	17.67	17.76	
standard deviation	± 3.645	± 3.831	-

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	TDV 0.5 mL

Reporting group description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	Placebo

Reporting group description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	TDV 0.5 mL

Reporting group description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	Placebo

Reporting group description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	TDV 0.5 mL

Reporting group description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	Placebo

Reporting group description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	TDV 0.5 mL

Reporting group description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	Placebo

Reporting group description:

Participants received placebo-matching TDV, 0.5 milliliters (mL), subcutaneous (SC) injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	TDV 0.5 mL

Reporting group description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Primary: Vaccine Efficacy (VE) of Two Doses of Tetravalent Dengue Vaccine (TDV) in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point title	Vaccine Efficacy (VE) of Two Doses of Tetravalent Dengue Vaccine (TDV) in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point description:

The Vaccine Efficacy is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific reverse transcriptase polymerase chain reaction (RT-PCR). The primary endpoint of vaccine efficacy was assessed using the number of confirmed dengue cases that occurred during Part 1. Per protocol Set (PPS) included all participants in the Full analysis set (FAS) who had no major protocol violations. FAS included all randomised participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Primary

End point timeframe:

30 days post-second vaccination (Day 120 [Month 4]) until the end of Part 1 (Month 15) when at least 120 cases of dengue fever were confirmed and minimum duration of participant follow-up was 12 months post-second vaccination

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6316	12700		
Units: number of cases				
number (not applicable)	149	61		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Assuming true VE of 60% and, virologically confirmed cases of dengue fever induced by any dengue serotype occurring from 30 days post 2nd vaccination (Day 120) until end of Part 1 would provide at least 90% power to rule out vaccine effect of ≤25%.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	19016
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.001 [2]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	80.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	73.3
upper limit	85.3

Notes:

[1] - VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.
[2] - Statistical significance was concluded if the lower bound of the 95% CI for the VE was above 25%. Since the hypotheses was tested in a confirmatory manner at a 2-sided significance level of 5%, the calculated p-value was compared with 0.025.

Secondary: VE of Two Doses of TDV in Preventing Hospitalization Due to Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point title	VE of Two Doses of TDV in Preventing Hospitalization Due to Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases requiring hospitalization due to virologically-confirmed dengue fever that occurred during Part 1 and Part 2. PPS included all participants in the FAS who had no major protocol violations. FAS included all randomised participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

From 30 days post-second vaccination (Day 120 [Month 4]) until the end of Part 2 (Month 21)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6316	12700		
Units: number of cases				
number (not applicable)	66	13		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	19016
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	< 0.001 [4]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	90.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	82.6
upper limit	94.7

Notes:

[3] - VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

[4] - Statistical significance was concluded if the lower bound of the 95% CI for the VE was above 0%. Since the hypotheses was tested in a confirmatory manner at a 2-sided significance level of 5%, the calculated p-value was compared with 0.025.

Secondary: VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Each Dengue Serotype

End point title	VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Each Dengue Serotype

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases that occurred during Part 1 and Part 2. PPS included all participants in the FAS who had no major protocol violations. FAS included all randomised participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

From 30 days post-second vaccination (Day 120 [Month 4]) until the end of Part 2 (Month 21)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6316	12700		
Units: number of cases				
number (not applicable)				
DENV-1	62	38		
DENV-2	80	8		
DENV-3	60	63		
DENV-4	5	5		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV
Statistical analysis description: DENV-1	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	19016
Analysis specification	Pre-specified
Analysis type	superiority[5]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	69.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.8
upper limit	79.9

Notes:

[5] - VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Statistical analysis title	VE of Two Doses of TDV
Statistical analysis description:	
DENV-4	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	19016
Analysis specification	Pre-specified
Analysis type	superiority[6]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	50.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.7
upper limit	85.8

Notes:

[6] - VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Statistical analysis title	VE of Two Doses of TDV
Statistical analysis description:	
DENV-3	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	19016
Analysis specification	Pre-specified
Analysis type	superiority[7]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	48.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.1
upper limit	64.1

Notes:

[7] - VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Statistical analysis title	VE of Two Doses of TDV
Statistical analysis description:	
DENV-2	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	19016
Analysis specification	Pre-specified
Analysis type	superiority[8]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	95.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	89.9
upper limit	97.6

Notes:

[8] - VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Secondary: VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype in Participants Dengue Seronegative at Baseline

End point title	VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype in Participants Dengue Seronegative at Baseline

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases that occurred during Part 1 and Part 2. PPS included all participants in the FAS who had no major protocol violations. FAS included all randomized participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with seronegative baseline status and with data available for analyses.

End point type	Secondary

End point timeframe:

From 30 days post-second vaccination (Day 120 [Month 4]) until the end of Part 2 (Month 21)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1726	3531		
Units: number of cases				
number (not applicable)	56	39		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	5257
Analysis specification	Pre-specified
Analysis type	superiority[9]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	66.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.1
upper limit	77.5

Notes:

[9] - VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Secondary: VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype in Participants Dengue Seropositive at Baseline

End point title	VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype in Participants Dengue Seropositive at Baseline

End point description:

VE is defined as 1 - (λv/λC), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases that occurred during Part 1 and Part 2. PPS included all participants in the FAS who had no major protocol violations. FAS included all randomized participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with seropositive baseline status and with data available for analyses.

End point type	Secondary

End point timeframe:

From 30 days post-second vaccination (Day 120 [Month 4]) until the end of Part 2 (Month 21)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4589	9167		
Units: number of cases				
number (not applicable)	150	75		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	13756
Analysis specification	Pre-specified
Analysis type	superiority[10]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	76.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.5
upper limit	81.9

Notes:

[10] - VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Secondary: VE of Two Doses of TDV in Preventing Virologically-Confirmed Severe Dengue Fever Induced by Any Dengue Serotype

End point title	VE of Two Doses of TDV in Preventing Virologically-Confirmed Severe Dengue Fever Induced by Any Dengue Serotype

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. Severe cases were determined by Adjudication Committee. VE was assessed using the number of severe cases due to virologically-confirmed dengue fever that occurred during Part 1 and Part 2. PPS included all participants in the FAS who had no major protocol violations. FAS included all randomized participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Secondary

End point timeframe:

From 30 days post-second vaccination (Day 120 [Month 4]) until the end of Part 2 (Month 21)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6316	12700		
Units: number of cases				
number (not applicable)	1	2		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	19016
Analysis specification	Pre-specified
Analysis type	superiority[11]
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	2.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-978.5
upper limit	91.1

Notes:

[11] - VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Secondary: Percentage of Participants With Solicited Local Injection Site Adverse Events (AEs) by Severity in the Safety Set Immunogenicity Subset

End point title	Percentage of Participants With Solicited Local Injection Site Adverse Events (AEs) by Severity in the Safety Set Immunogenicity Subset

End point description:

Solicited local AEs at injection site are defined as pain, erythema and swelling that occurred within 7 days after each vaccination (first vaccination [V1] or second vaccination [V2]). The participant/legal guardian recorded the severity of each AE (except erythema and swelling) according to the diary card instruction as none, mild, moderate, or severe. Severity grades for erythema and swelling were derived from the recorded diameters. Percentages were rounded off to the nearest single decimal place except

the data points where rounding-up may lead to data misinterpretation. The Safety Set-Immunogenicity Subset included all randomised participants in the safety/immunogenicity subset who received at least 1 dose of the trial vaccines (TDV or placebo). Subjects analysed is the number of participants with data available for analyses. 'n' indicates the number of participants with data available for analyses for the specified category. 'Y' indicates years.

End point type	Secondary

End point timeframe:

Days 1 through 7 after each vaccination

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1329	2663		
Units: percentage of participants				
number (not applicable)				
<6Y:After V1:Pain: Mild (n=169,327)	19.5	21.1		
<6Y:After V1: Pain:Moderate (n=169,327)	1.2	2.1		
<6 Y: After V1: Pain:Severe (n=169,327)	0.6	0.3		
<6 Y: After V1: Erythema:Mild (n=169,327)	0.6	0.6		
<6 Y:After V1 :Erythema;Moderate (n=169,327)	0	0.6		
<6 Y: After V1:Erythema; Severe (n=169,327)	0	0		
<6 Y: After V1:Swelling: Mild (n=169,327)	0.6	1.9		
<6 Y:After V1:Swelling: Moderate (n=169,327)	0	0.9		
<6 Y:After V1 :Swelling: Severe(n=169,327)	0	0		
<6 Y:After V2:Pain: Mild (n=165,324)	13.3	18.2		
<6 Y:After V2: Pain:Moderate (n=165,324)	1.2	2.5		
<6 Y:After V2:Pain: Severe (n=165,324)	0	0		
<6 Y:After V2: Erythema; Mild (n=165,322)	0	0.6		
<6 Y:After V2;Erythema; Moderate (n=165,322)	0	0		
<6 Y:After V2:Erythema: Severe (n=165,322)	0	0		
<6 Y:After V2:Swelling: Mild (n=164,323)	0.6	0.9		
<6 Y:After V2:Swelling: Moderate(n=164,323)	0	0.6		
<6 Y:After V2: Swelling: Severe (n=164,323)	0	0		
≥6 Y:After V1: Pain: Mild (n=1143,2284)	16.9	23.4		
≥6 Y:After V1: Pain: Moderate (n=1143,2284)	2.2	3.9		
≥6 Y:After V1:Pain: Severe (n=1143,2284)	0.3	0.7		
≥6 Y: After V1: Erythema: Mild (n=1140,2276)	0	1.0		

≥6 Y:After V1: Erythema: Moderate (n=1140,2276)	0	0		
≥6 Y:After V1:Erythema;Severe (n=1140,2276)	0	0		
≥6 Y:After V1: Swelling: Mild n=1140,2272)	0.4	1.2		
≥6 Y:After V1:Swelling: Moderate (n=1140,2272)	0	0		
≥6 Y:After V1:Swelling: Severe (n=1140,2272)	0	0		
≥6 Y:After V2: Pain:Mild (n=1116,2251)	10.7	19.7		
≥6 Y:After V2: Pain;Moderate (n=1116,2251)	1.5	3.2		
≥6 Y:After V2:Pain: Severe (n=1116,2251)	0.3	0.6		
≥6 Y:After V2:Erythema: Mild (n=1113,2248)	0.0898	0.9		
≥6 Y:After V2:Erythema:Moderate (n=1113,2248)	0	0		
≥6 Y:After V2: Erythema:Severe (n=1113,2248)	0	0		
≥6 Y: AfterV2:Swelling: Mild (n=1112,2246)	0.0899	0.6		
≥6 Y:After V2:Swelling:Moderate (n=1112,2246)	0	0		
≥6 Y:After V2:Swelling: Severe(n=1112,2246)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Solicited Systemic Adverse Events (AEs) by Severity in the Safety Set Immunogenicity Subset

End point title	Percentage of Participants With Solicited Systemic Adverse Events (AEs) by Severity in the Safety Set Immunogenicity Subset

End point description:

Solicited systemic AEs were recorded within 14 days after each vaccination (first vaccination [V1] or second vaccination [V2]).. In children <6 years defined as fever, irritability/fussiness, drowsiness, loss of appetite. In children ≥6 years defined as fever, headache, asthenia, malaise, myalgia. Participant/legal guardian recorded severity of each AE (except fever) according to diary card instruction: none, mild, moderate (mod.), severe (sev.). Severity grades for fever were derived from recorded body temperature measurements using increments published by Brighton Collaboration. Percentages were rounded off to nearest single decimal place except data points where rounding-up may lead to data misinterpretation. SS-Immunogenicity Subset: all randomised participants in safety/immunogenicity subset who received at least 1 dose of trial vaccine (TDV/placebo). 'n': number of participants with data available for specified category. 'Y'= Years

End point type	Secondary

End point timeframe:

Days 1 through 14 after each vaccination on Day 1 (Month 0) and Day 90 (Month 3)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1329	2663		
Units: percentage of participants				
number (not applicable)				
<6 Y: After V1;Irritability:Mild (n= 169,325)	8.3	7.7		
<6Y: After V1: Irritability:Moderate (n=169,325)	0.6	0.9		
<6Y: After V1: Irritability: Severe (n= 169,325)	0	0.3		
<6Y: After V1: Drowsiness: Mild (n= 169,325)	10.1	8.3		
<6 Y:After V1: Drowsiness:Moderate (n= 169,325)	0	2.2		
<6Y:After V1: Drowsiness:Severe (n= 169,325)	0	0.6		
<6Y: After V1:Loss of Appetite:Mild (n=169,325)	7.1	12.3		
<6Y:AfterV1:Loss of Appetite:Moderate(n= 169,325)	1.8	1.2		
<6 Y:After V1:Loss of Appetite:Severe(n= 169,325)	0.6	0.6		
<6 Y:After V1: Fever; 38.0-<38.5 (n=153,311)	3.3	3.9		
<6 Y: After V1: Fever: 38.5-<39.0 (n=153,311)	2.0	1.9		
<6 Y: After V1: Fever: 39.0-<39.5 (n=153,311)	2.0	1.9		
<6 Y: After V1: Fever: 39.5-<40.0 (n=153,311)	0.7	1.0		
<6 Y: After V1: Fever: ≥40.0 (n=153,311)	0	0		
<6 Y: After V2: Irritability: Mild (n=143,284)	2.1	5.3		
<6 Y:After V2: Irritability:Moderate (n=143,284)	0	0.4		
<6 Y: After V2: Irritability: Severe (n=143,284)	0	0.4		
<6 Y: After V2; Drowsiness: Mild (n=143,284)	4.9	6.0		
<6 Y:After V2: Drowsiness:Moderate (n=143,284)	0	1.1		
<6 Y: After V2: Drowsiness: Severe (n=143,284)	0	0		
<6 Y: After V2: Loss of Appetite:Mild (n=143,284)	4.9	6.0		
<6Y:After V2:Loss of Appetite:Moderate(n=143,284)	0.7	1.1		
<6Y:After V2:Loss of Appetite:Severe (n=143,284)	0.7	0.4		
<6 Y:After V2: Fever: 38.0<38.5 (n=158,313)	4.4	1.3		
<6 Y: After V2: Fever: 38.5-<39.0 (n=158,313)	1.3	3.5		
<6 Y: After V2: Fever; 39.0-<39.5 (n=158,313)	1.3	1.3		
<6 Y: After V2: Fever: 39.5-<40.0 (n=158,313)	0	0.6		
<6 Y: After V2: Fever: 40.0-<40.5 (n=158,313)	0.6	0.3		

<6 Y: After V2: Fever; ≥40.5 (n=158,313)	0	0		
≥6 Y: After V1: Headache:Mild (n=1142, 2284)	17.8	17.5		
≥6 Y: After V1: Headache: Moderate (n=1142, 2284)	3.4	5.3		
≥6 Y: After V1: Headache: Severe (n=1142, 2284)	1.7	1.8		
≥6 Y: After V1: Asthenia: Mild (n=1142, 2285)	8.8	8.8		
≥6 Y: After V1: Asthenia: Moderate (n=1142, 2285)	2.8	2.8		
≥6 Y: After V1: Asthenia: Severe (n=1142, 2285)	0.5	0.8		
≥6 Y: After V1: Malaise: Mild (n=1142, 2283)	11.1	11.8		
≥6 Y :After V1: Malaise: Moderate (n=1142, 2283)	2.3	3.4		
≥6 Y: After V1: Malaise:Severe (n=1142, 2283)	0.8	1.0		
≥6 Y: After V1: Myalgia: Mild (n=1142, 2283)	11.8	14.1		
≥6 Y: After V1: Myalgia: Moderate (n=1142, 2283)	1.9	2.9		
≥6 Y: After V1: Myalgia:Severe (n=1142, 2283)	0.6	0.9		
≥6 Y: After V1: Fever: 38.0-<38.5 (n=1052, 2088)	3.0	3.0		
≥6 Y: After V1: Fever: 38.5-<39.0 (n=1052, 2088)	1.8	2.0		
≥6 Y: After V1; Fever: 39.0-<39.5 (n=1052, 2088)	1.0	0.5		
≥6 Y: After V1: Fever: 39.5-<40.0 (n=1052, 2088)	0.4	0.4		
≥6 Y: After V1 : Fever: 40.0-<40.5 (n=1052, 2088)	0.0951	0.0479		
≥6 Y:After V1: Fever: 40.5-<41.0 (n=1052, 2088)	0.0951	0		
≥6 Y: After V1: Fever: >=41.0 (n=1052, 2088)	0	0		
≥6 Y: After V2; Headache:Mild (n=1117, 2248)	10.2	10.4		
≥6 Y: After V2:Headache: Moderate (n=1117, 2248)	2.9	3.5		
≥6 Y: After V2: Headache: Severe (n=1117, 2248)	1.1	1.3		
≥6 Y: After V2: Asthenia: Mild (n=1117, 2248)	5.6	6.6		
≥6 Y:After V2:Asthenia: Moderate (n=1117, 2248)	1.6	1.9		
≥6 Y: After V2: Asthenia: Severe (n=1117, 2248)	0.4	0.7		
≥6 Y: After V2; Malaise: Mild (n=1117, 2248)	6.8	8.1		
≥6 Y: After V2: Malaise:Moderate (n=1117, 2248)	1.8	1.9		
≥6 Y: After V2: Malaise:Severe (n=1117, 2248)	0.8	1.0		
≥6 Y: After V2: Myalgia:Mild (n=1117, 2248)	7.6	10.7		
≥6 Y: After V2 : Myalgia:Moderate (n=1117, 2248)	1.3	2.0		

≥6 Y: After V2: Myalgia:Severe (n=1117, 2248)	0.4	0.9		
≥6 Y: After V2:Fever: 38.0-<38.5 (n= 1056, 2142)	3.4	2.0		
≥6 Y: After V2: Fever: 38.5-<39.0 (n= 1056, 2142)	1.2	1.5		
≥6 Y: After V2: Fever: 39.0-<39.5 (n= 1056, 2142)	1.1	0.7		
≥6 Y: After V2: Fever: 39.5-<40.0 (n= 1056, 2142)	0.4	0.5		
≥6 Y: After V2: Fever: 40.0-<40.5 (n= 1056, 2142)	0	0.0467		
≥6 Y: After V2: Fever: >=40.5 (n= 1056, 2142)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Any Unsolicited Adverse Events (AEs) in the Safety Set Immunogenicity Subset

End point title	Percentage of Participants With Any Unsolicited Adverse Events (AEs) in the Safety Set Immunogenicity Subset

End point description:

An AE is defined as any untoward medical occurrence in a clinical investigation participant administered a trial vaccine; it does not necessarily have to have a causal relationship with trial vaccine administration. Unsolicited AEs are any AEs that are not solicited local or systemic AEs, as defined by this study. The SS-Immunogenicity Subset included all randomized participants in the safety/immunogenicity subset who received at least 1 dose of the trial vaccines (TDV or placebo). 'n' indicates the number of participants with data available for analysis for the specified category.

End point type	Secondary

End point timeframe:

Days 1 through 28 after each vaccination on Day 1 (Month 0) and Day 90 (Month 3)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1329	2663		
Units: percentage of participants				
number (not applicable)				
After First Vaccination (n=1329, 2663)	11.6	11.1		
After Second Vaccination (n=1301, 2606)	9.2	9.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Serious Adverse Events (SAEs) During

Parts 1 and 2

End point title	Percentage of Participants With Serious Adverse Events (SAEs) During Parts 1 and 2

End point description:

An AE is defined as any untoward medical occurrence in a clinical investigation participant administered a trial vaccine; it does not necessarily have to have a causal relationship with trial vaccine administration. A serious adverse event (SAE) is any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity, is a congenital anomaly / birth defect or is medically important due to other reasons than the above-mentioned criteria. Percentages were rounded off to the nearest single decimal place. The SS included all randomized participants who received at least one dose of the investigational product (IP) (TDV or placebo).'n' is the number of participants at risk at the start of the specified analysis period.

End point type	Secondary

End point timeframe:

From Day 1 until the end of Parts 1 (Month 15) and 2 (Month 21)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6687	13380		
Units: percentage of participants				
number (not applicable)				
Part 1 (n=6687, 13380)	3.8	3.1		
Part 2 (n=6519, 13303)	1.2	1.1		
Part 1 and 2 combined (n=6687, 13380)	4.8	4.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Fatal SAEs and SAEs Related to Study Drug During the First and Second Half of Part 3

End point title	Percentage of Participants With Fatal SAEs and SAEs Related to Study Drug During the First and Second Half of Part 3

End point description:

AE is defined as any untoward medical occurrence in a clinical investigation participant administered a trial vaccine; it does not necessarily have to have a causal relationship with trial vaccine administration. A SAE is any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity, is a congenital anomaly / birth defect or is medically important due to other reasons than the above-mentioned criteria. Percentages were rounded off to the nearest single decimal place except the data points where rounding-up may lead to data misinterpretation. SS: all randomized participants who received at least one dose of IP (TDV or placebo). Subjects analysed: number of participants with data available for analyses. 'n' indicates number of participants at risk at start of specified analysis period.

End point type	Secondary

End point timeframe:

First and Second half (18 months each) of Part 3 (up to 3 years, beginning at Month 22)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6487	12961		
Units: percentage of participants				
number (not applicable)				
Fatal SAEs:First Half of Part 3(n=6487,12961)	0.0308	0.0386		
SAEs: First Half of Part 3 (n=6487, 12961)	0	0		
Fatal SAEs:Second Half of Part 3(n=6340, 12660)	0.0631	0.0474		
SAEs: Second Half of Part 3 (n=6340, 12660)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Seropositivity Rate for Each of the Four Dengue Serotypes in the Immunogenicity Subset

End point title	Seropositivity Rate for Each of the Four Dengue Serotypes in the Immunogenicity Subset

End point description:

Seropositivity rate, defined as the percentage of participants seropositive, is derived from the titers of dengue-neutralizing antibodies. Seropositivity is defined as a reciprocal neutralizing titer ≥10. The four DENV serotypes are DENV-1, DENV-2, DENV-3 and DENV-4. Percentages were rounded off to the nearest single decimal place except the data points where rounding-up may lead to data misinterpretation. Per-Protocol Set for Immunogenicity (PPSI): all participants in Full Analysis Set for Immunogenicity (FASI) who had no major protocol violations. The FASI were based on FAS & included all randomised participants in subset for whom a valid pre-dosing and at least one valid post-dosing blood sample have been received for immunogenicity. 'n' indicates the number of participants with data available for analysis at the specified time point.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 (Baseline), post-first vaccination on Month 1, pre-vaccination on Month 3; post-second vaccination at Months 4, 9 and 15, and then annually (up to 3 years)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1247	2518		
Units: percentage of participants				
number (not applicable)				
Baseline: DENV-1 (n=1247, 2518)	65.5	64.3		
Baseline: DENV-2 (n=1247, 2518)	70.3	69.6		
Baseline: DENV-3 (n=1247, 2518)	63.7	63.5		
Baseline: DENV-4 (n=1247, 2518)	63.2	63.5		

Month 1: DENV-1 (n=1165, 2353)	65.0	98.0		
Month 1: DENV-2 (n=1164, 2353)	70.0	99.5		
Month 1: DENV-3 (n=1164, 2353)	64.0	98.7		
Month 1: DENV-4 (n=1165, 2353)	62.7	97.1		
Month 3: DENV-1 (n=1244, 2515)	66.9	97.1		
Month 3: DENV-2 (n=1244, 2515)	71.2	99.7		
Month 3: DENV-3 (n=1243, 2515)	63.6	98.1		
Month 3: DENV-4 (n=1244, 2515)	63.6	97.3		
Month 4: DENV-1 (n=1131, 2262)	67.6	99.8		
Month 4: DENV-2 (n=1131, 2262)	71.8	99.912		
Month 4: DENV-3 (n=1131, 2262)	65.0	99.9		
Month 4: DENV-4 (n=1131, 2262)	65.2	99.912		
Month 9: DENV-1 (n=1085, 2196)	67.5	98.3		
Month 9: DENV-2 (n=1085, 2196)	73.5	100.0		
Month 9: DENV-3 (n=1085, 2196)	65.2	98.8		
Month 9: DENV-4 (n=1085, 2196)	65.2	99.0		
Month 15: DENV-1 (n=1115, 2213)	67.7	97.6		
Month 15: DENV-2 (n=1115, 2214)	70.4	99.955		
Month 15: DENV-3 (n=1115, 2215)	64.3	97.7		
Month 15: DENV-4 (n=1115, 2215)	66.0	98.4		
Year 1: DENV-1 (n=942, 1904)	69.6	97.0		
Year 1: DENV-2 (n=942, 1904)	72.0	99.9		
Year 1: DENV-3 (n=942, 1904)	67.5	97.3		
Year 1: DENV-4 (n=942, 1904)	68.6	98.3		
Year 2: DENV-1 (n=955, 1921)	71.5	95.7		
Year 2: DENV-2 (n=955, 1921)	73.7	99.948		
Year 2: DENV-3 (n=955, 1921)	68.8	95.5		
Year 2: DENV-4 (n=955, 1921)	70.7	98.0		
Year 3: DENV-1 (n=1023, 2049)	72.5	94.9		
Year 3: DENV-2 (n=1023, 2049)	73.5	99.9		
Year 3: DENV-3 (n=1023, 2049)	70.2	95.7		
Year 3: DENV-4 (n=1023, 2049)	71.1	96.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Seropositivity Rate for Multiple Dengue Serotypes in the Immunogenicity Subset

End point title	Seropositivity Rate for Multiple Dengue Serotypes in the Immunogenicity Subset

End point description:

Seropositivity rate for multiple Dengue serotypes, defined as the percentage of participants seropositive for any one (monovalent), two (bivalent), three (trivalent), and four (tetravalent) dengue serotypes, as well as at least bivalent (seropositive for ≥2 dengue serotypes) and at least trivalent (seropositive for ≥3 dengue serotypes), is derived from the titers of dengue-neutralizing antibodies. Seropositive response = reciprocal neutralizing titer ≥ 10. Four DENV serotypes: DENV-1, DENV-2, DENV-3, DENV-4. Percentages were rounded off to the nearest single decimal place except the data points where rounding-up may lead to data misinterpretation. PPSI: all participants in FASI without major protocol violations. FASI based on FAS & included all randomized participants in subset for whom a valid pre-dosing and at least 1 valid post-dosing blood sample was received for immunogenicity. ‘n’ indicates number of participants with data available for analysis at the specified time point.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 (Baseline), post-first vaccination on Month 1, pre-vaccination on Month 3; post-second vaccination at Months 4, 9 and 15, and then annually (up to 3 years)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1247	2518		
Units: percentage of participants				
number (not applicable)				
Baseline: Monovalent (n=1247, 2518)	5.5	6.6		
Baseline: Bivalent (n=1247, 2518)	3.8	2.4		
Baseline: Trivalent (n=1247, 2517)	2.7	2.9		
Baseline: Tetravalent (n=1247, 2517)	60.4	60.2		
Baseline: At Least Bivalent (n=1247, 2518)	66.9	65.5		
Baseline: At Least Trivalent (n=1247, 2517)	63.1	63.1		
Month 1: Monovalent (n=1165, 2353)	7.4	0.3		
Month 1: Bivalent (n=1165, 2353)	2.8	0.6		
Month 1: Trivalent (n=1164, 2353)	3.2	3.7		
Month 1: Tetravalent(n=1164, 2353)	59.8	95.2		
Month 1: At Least Bivalent (n=1165, 2353)	65.8	99.4		
Month 1: At Least Trivalent (n=1164, 2353)	63.0	98.9		
Month 3: Monovalent (n=1244, 2353)	6.8	0.4		
Month 3: Bivalent (n=1244, 2353)	3.1	1.1		
Month 3: Trivalent (n=1244, 2353)	3.1	3.7		
Month 3: Tetravalent (n=1243, 2353)	60.8	94.6		
Month 3: At Least Bivalent (n=1244, 2353)	67.0	99.4		
Month 3: At Least Trivalent (n=1244, 2353)	63.8	98.3		
Month 4: Monovalent (n=1131, 2262)	6.6	0		
Month 4: Bivalent (n=1131, 2262)	2.6	0.088		
Month 4: Trivalent (n=1131, 2262)	2.5	0.1		
Month 4: Tetravalent (n=1131, 2262)	62.6	99.7		
Month 4: At Least Bivalent (n=1131, 2262)	67.6	99.956		
Month 4: At Least Trivalent(n=1131, 2262)	65.1	99.9		
Month 9: Monovalent (n=1085, 2196)	7.7	0.091		
Month 9: Bivalent (n=1085, 2196)	3.4	0.8		
Month 9: Trivalent (n=1085, 2196)	2.0	2.1		
Month 9: Tetravalent (n=1085, 2196)	62.7	97.0		
Month 9: At Least Bivalent (n=1085, 2196)	68.1	99.909		
Month 9: At Least Trivalent (n=1085, 2196)	64.7	99.1		
Month 15: Monovalent (n=1115, 2215)	3.9	0.5		
Month 15: Bivalent (n=1115, 2215)	3.6	1.4		

Month 15: Trivalent (n=1115, 2215)	2.1	2.2		
Month 15: Tetravalent (n=1115, 2215)	62.8	96.0		
Month 15: At Least Bivalent (n=1115, 2215)	68.4	99.5		
Month 15: At Least Trivalent (n=1115, 2215)	64.8	98.1		
Year 1: Monovalent (n= 942,1904)	3.5	0.7		
Year 1: Bivalent (n= 942,1904)	1.9	1.5		
Year 1: Trivalent (n= 942,1904)	2.2	2.2		
Year 1: Tetravalent (n= 942,1904)	65.9	95.5		
Year 1: At Least Bivalent (n= 942,1904)	70.1	99.3		
Year 1: At Least Trivalent(n= 942,1904)	68.2	97.7		
Year 2: Monovalent (n= 955,1921)	2.9	1.1		
Year 2: Bivalent (n= 955,1921)	2.5	1.9		
Year 2: Trivalent (n= 955,1921)	1.8	3.7		
Year 2: Tetravalent (n= 955,1921)	67.9	93.3		
Year 2: At Least Bivalent (n= 955,1921)	72.1	98.9		
Year 2: At Least Trivalent (n= 955,1921)	69.6	97.0		
Year 3:Monovalent (n= 1023,2049)	2.6	1.6		
Year 3: Bivalent (n= 1023,2049)	1.9	2.4		
Year 3: Trivalent (n= 1023,2049)	2.5	3.7		
Year 3: Tetravalent (n= 1023,2049)	68.3	92.3		
Year 3: At Least Bivalent (n= 1023,2049)	72.7	98.3		
Year 3: At Least Trivalent (n= 1023,2049)	70.9	95.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers (GMTs) of Neutralizing Antibodies for Each of the Four Dengue Serotypes in the Immunogenicity Subset

End point title	Geometric Mean Titers (GMTs) of Neutralizing Antibodies for Each of the Four Dengue Serotypes in the Immunogenicity Subset

End point description:

GMTs of neutralizing antibodies were measured via microneutralization test 50% (MNT50). The four DENV serotypes are DENV-1, DENV-2, DENV-3 and DENV-4. PPSI: all participants in FASI who had no major protocol violations. The FASI were based on FAS & included all randomized participants in subset for whom a valid pre-dosing and at least one valid post-dosing blood sample have been received for immunogenicity. ‘n’ indicates the number of participants with data available for analysis at the specified time point.

End point type	Secondary

End point timeframe:

Pre-vaccination on Day 1 (Baseline), post-first vaccination on Month 1, pre-vaccination on Month 3; post-second vaccination at Months 4, 9 and 15, and then annually (up to 3 years)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1247	2518		
Units: titres				
geometric mean (confidence interval 95%)				
Baseline: DENV-1 (n=1247,2518)	128.6 (109.3 to 151.4)	120.3 (107.3 to 134.8)		
Baseline: DENV-2 (n=1247,2518)	197.4 (167.8 to 232.2)	186.0 (165.9 to 208.4)		
Baseline: DENV-3 (n=1247,2518)	109.4 (93.8 to 127.6)	108.7 (97.6 to 121.1)		
Baseline: DENV-4 (n=1247,2518)	80.8 (70.2 to 93.1)	76.2 (69.2 to 83.9)		
Month 1: DENV-1 (n=1165,2353)	127.5 (107.7 to 150.9)	1031.5 (944.4 to 1126.6)		
Month 1: DENV-2 (n=1164,2353)	197.2 (166.7 to 233.4)	6575.7 (6237.2 to 6932.5)		
Month 1: DENV-3 (n=1164,2353)	108.6 (92.8 to 127.1)	1133.8 (1050.4 to 1223.8)		
Month 1: DENV-4 (n=1165,2353)	77.6 (67.2 to 89.7)	653.4 (607.0 to 703.4)		
Month 3: DENV-1 (n=2114,2515)	126.3 (107.9 to 148.0)	828.7 (760.6 to 902.8)		
Month 3: DENV-2 (n=2114,2515)	201.0 (171.3 to 236.0)	3598.5 (3425.0 to 3780.8)		
Month 3: DENV-3 (n=2113,2515)	103.9 (89.5 to 120.7)	714.2 (661.1 to 771.6)		
Month 3: DENV-4 (n=2114,2515)	77.8 (67.8 to 89.3)	463.9 (431.3 to 498.9)		
Month 4: DENV-1 (n=1131,2262)	139.0 (117.6 to 164.3)	1059.2 (981.6 to 1143.0)		
Month 4: DENV-2 (n=1131,2262)	215.3 (181.7 to 255.0)	3646.7 (3480.0 to 3821.3)		
Month 4: DENV-3 (n=1131,2262)	114.5 (97.7 to 134.3)	986.7 (924.5 to 1053.0)		
Month 4: DENV-4 (n=1131,2262)	86.2 (74.5 to 99.8)	630.0 (593.2 to 668.9)		
Month 9: DENV-1 (n=1085,2196)	130.5 (110.3 to 154.4)	666.6 (611.8 to 726.2)		
Month 9: DENV-2 (n=1085,2196)	225.7 (190.5 to 267.3)	2521.0 (2392.4 to 2656.5)		
Month 9: DENV-3 (n=1085,2196)	105.3 (89.9 to 123.3)	513.0 (474.2 to 555.1)		
Month 9: DENV-4 (n=1085,2196)	84.4 (72.9 to 97.8)	390.0 (363.6 to 418.4)		
Month 15: DENV-1 (n=1115,2213)	139.2 (117.6 to 164.7)	584.1 (534.9 to 637.8)		
Month 15: DENV-2(n=1115,2214)	211.8 (178.5 to 251.3)	1977.3 (1871.7 to 2088.8)		
Month 15: DENV-3 (n=1115,2215)	97.3 (83.3 to 113.5)	383.9 (354.0 to 416.3)		
Month 15: DENV-4 (n=1115,2215)	99.9 (86.0 to 116.0)	408.0 (379.6 to 438.6)		
Year 1: DENV-1 (n=942,1904)	161.3 (134.6 to 193.3)	567.8 (516.0 to 624.7)		

Year 1: DENV-2 (n=942,1904)	183.1 (154.0 to 217.7)	1123.9 (1054.1 to 1198.3)		
Year 1: DENV-3 (n=942,1904)	111.0 (94.1 to 130.9)	377.7 (346.2 to 412.2)		
Year 1: DENV-4 (n=942,1904)	98.6 (84.6 to 115.0)	345.0 (319.6 to 372.5)		
Year 2: DENV-1 (n=955,1921)	205.1 (170.9 to 246.1)	513.2 (465.9 to 565.3)		
Year 2: DENV-2 (n=955,1921)	208.1 (175.3 to 246.9)	896.4 (839.2 to 957.5)		
Year 2: DENV-3 (n=955,1921)	127.5 (108.2 to 150.2)	323.2 (295.7 to 353.2)		
Year 2: DENV-4 (n=955,1921)	110.4 (94.8 to 128.4)	283.8 (262.9 to 306.4)		
Year 3: DENV-1 (n=1023,2049)	213.3 (179.4 to 253.6)	483.1 (440.7 to 529.7)		
Year 3: DENV-2 (n=1023,2049)	193.6 (164.6 to 227.6)	727.5 (682.4 to 775.5)		
Year 3: DENV-3 (n=1023,2049)	139.8 (119.3 to 163.7)	327.9 (301.4 to 356.8)		
Year 3: DENV-4 (n=1023,2049)	107.6 (93.1 to 124.4)	244.4 (226.7 to 263.6)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point title	VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases due to virologically-confirmed dengue fever that occurred during the first half of Part 3.PPS included all participants in the FAS who had no major protocol violations. FAS included all randomized participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Other pre-specified

End point timeframe:

First half of Part 3 (18 months beginning at Month 22)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6236	12510		
Units: number of cases				
number (not applicable)	228	252		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV

Statistical analysis description:

VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	18746
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	47.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.1
upper limit	56

Other pre-specified: VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point title	VE of Two Doses of TDV in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases due to virologically-confirmed dengue fever that occurred during the second half of Part 3. . PPS included all participants in the FAS who had no major protocol violations. FAS included all randomized participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Other pre-specified

End point timeframe:

Second half of Part 3 (18 months beginning at Month 40)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6102	12224		
Units: number of cases				
number (not applicable)	52	49		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV

Statistical analysis description:

VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	18326
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	55.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	34.5
upper limit	70

Other pre-specified: VE of Two Doses of TDV in Preventing Hospitalization Due to Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point title	VE of Two Doses of TDV in Preventing Hospitalization Due to Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases requiring hospitalization due to virologically-confirmed dengue fever that occurred during the first half of Part 3. PPS included all participants in the FAS who had no major protocol violations. FAS included all randomized participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Other pre-specified

End point timeframe:

First half of Part 3 (18 months beginning at Month 22)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6236	12510		
Units: number of cases				
number (not applicable)	43	24		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV

Statistical analysis description:

VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	18746
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	73.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	56.3
upper limit	83.9

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype From 30 Days Post-Booster Vaccination (Day 30 Booster [b] (Month 1b)) Until the End of Part 4

End point title	VE of a TDV Booster Dose in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype From 30 Days Post-Booster Vaccination (Day 30 Booster [b] (Month 1b)) Until the End of Part 4

End point description:

The VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases.Per-Protocol Set-Booster (PPS-B) included all participants in the FAS-B who had no major protocol violations. Full Analysis Set-Booster (FAS-B) included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30 booster [b] (Month 1b)) until the end of Part 4 (Month 13b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)	93	39		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	79.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.1
upper limit	85.9

Other pre-specified: VE of Two Doses of TDV in Preventing Hospitalization Due to Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point title	VE of Two Doses of TDV in Preventing Hospitalization Due to Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases requiring hospitalization due to virologically-confirmed dengue fever that occurred during the second half of Part 3.PPS included all participants in the FAS who had no major protocol violations. FAS included all randomized participants who received at least 1 dose of the trial vaccines. Subjects analysed is the number of participants with data available for analyses.

End point type	Other pre-specified

End point timeframe:

Second half of Part 3 (18 months beginning at Month 40)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6102	12224		
Units: number of cases				
number (not applicable)	15	2		

Statistical analyses

Statistical analysis title	VE of Two Doses of TDV

Statistical analysis description:

VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	18326
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	93.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	72.4
upper limit	98.6

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Each Dengue Serotype From 30 days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Each Dengue Serotype From 30 days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 4 (Month 13b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)				
DENV-1	32	15		
DENV-2	31	9		
DENV-3	4	3		
DENV-4	26	12		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	76.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.1
upper limit	87.4

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	77.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.8
upper limit	88.5

Statistical analysis title	VE of a TDV Booster Dose (DENV-3)
Statistical analysis description: VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	62
Confidence interval	
level	95 %
sides	2-sided
lower limit	-69.7
upper limit	91.5

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)
Statistical analysis description: VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	85.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	69.9
upper limit	93.2

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any And Each Dengue Serotype in Dengue Seronegative Participants at Baseline From 30 Days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any And Each Dengue Serotype in Dengue Seronegative Participants at Baseline From 30 Days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms,

respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted only once for the "Any Dengue Serotype" category but counted separately for each dengue serotype they belong to. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). Subjects analysed is the number of participants with seronegative baseline status and with data available for analyses.

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 4 (Month 13b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	986	1928		
Units: number of cases				
number (not applicable)				
Any Dengue Serotype	26	11		
DENV-1	14	4		
DENV-2	5	1		
DENV-3	2	2		
DENV-4	5	4		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	86
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.6
upper limit	95.4

Statistical analysis title	VE of a TDV Booster Dose (Any Dengue Serotype)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a

factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	79.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.8
upper limit	89.7

Statistical analysis title	VE of a TDV Booster Dose (DENV-3)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	42.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-307.5
upper limit	92

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-45.1
upper limit	89.5

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	89.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.5
upper limit	98.8

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any and Each Dengue Serotype in Dengue Seropositive Participants at Baseline From 30 Days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any and Each Dengue Serotype in Dengue Seropositive Participants at Baseline From 30 Days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point description:

VE is defined as 1 - (λv/λC), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted only once for the "Any Dengue Serotype" category but counted separately for each dengue serotype they belong to. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). Subjects analysed is the number of participants with seropositive baseline status and with data available for analyses.

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 4 (Month 13b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1995	4036		
Units: number of cases				
number (not applicable)				
Any Dengue Serotype	67	28		
DENV-1	18	11		
DENV-2	26	8		
DENV-3	2	1		
DENV-4	21	8		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (Any Dengue Serotype)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	79.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	68.3
upper limit	86.9

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	69.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.4
upper limit	85.8

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	81
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.2
upper limit	91.6

Statistical analysis title	VE of a TDV Booster Dose (DENV-3)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	75.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-168.8
upper limit	97.8

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	84.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	66.6
upper limit	93.2

Other pre-specified: VE of a TDV Booster Dose in Preventing Hospitalization Due to Virologically Confirmed Dengue Fever Induced by Any Dengue Serotype From 30 Days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point title	VE of a TDV Booster Dose in Preventing Hospitalization Due to Virologically Confirmed Dengue Fever Induced by Any Dengue Serotype From 30 Days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases requiring hospitalization due to virologically-confirmed dengue fever. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 4 (Month 13b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)	24	3		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	93.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	79.3
upper limit	98.1

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Severe Dengue Fever Induced by Any Dengue Serotype From 30 days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Severe Dengue Fever Induced by Any Dengue Serotype From 30 days Post-Booster Vaccination (Day 30b [Month 1b]) Until the End of Part 4

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. Severe cases were determined by Adjudication Committee. VE was assessed using the number of severe cases due to virologically-confirmed dengue fever.. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 4 (Month 13b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)	1	0		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	-849.4
upper limit	100

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype During Part 5

End point title	VE of a TDV Booster Dose in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype During Part 5

End point description:

The VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted only once for the any dengue serotype. The Per-Protocol Set-Booster (PPS-B) included all participants in the FAS-B who had no major protocol violations. The Full Analysis Set-Booster (FAS-B) included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From Month 14b until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2935	5865		
Units: number of cases				
number (not applicable)	66	45		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	8800
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	67.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.1
upper limit	77.5

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Each Dengue Serotype During Part 5

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Each Dengue Serotype During Part 5

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted separately for each dengue serotype. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From Month 14b until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2935	5865		
Units: number of cases				
number (not applicable)				
DENV-1	19	17		
DENV-2	18	5		
DENV-3	20	20		
DENV-4	10	3		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	8800
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	56.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.2
upper limit	77.4

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8800
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	86.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	63.8
upper limit	95

Statistical analysis title	VE of a TDV Booster Dose (DENV-3

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8800
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	51.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.9
upper limit	73.9

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8800
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	85.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	47.4
upper limit	96

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any And Each Dengue Serotype in Dengue Seronegative Participants at Baseline During Part 5

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any And Each Dengue Serotype in Dengue Seronegative Participants at Baseline During Part 5

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted only once for the "Any Dengue Serotype" category but counted separately for each dengue serotype they belong to.The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). Subjects analysed is the number of participants with seronegative baseline status and with data available for analyses.

End point type	Other pre-specified

End point timeframe:

From Month 14b until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	974	1908		
Units: number of cases				
number (not applicable)				
Any Dengue Serotype	20	12		
DENV-1	7	6		
DENV-2	5	1		

DENV-3	4	5		
DENV-4	4	0		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (Any Dengue Serotype)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2882
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	70.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	39.1
upper limit	85.5

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2882
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.1
upper limit	100

Statistical analysis title	VE of a TDV Booster Dose (DENV-3)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	2882
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	36.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-138.1
upper limit	82.9

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2882
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	57.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.2
upper limit	85.7

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2882
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	90
Confidence interval	
level	95 %
sides	2-sided
lower limit	14
upper limit	98.8

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any and Each Dengue Serotype in Dengue Seropositive Participants at Baseline During Part 5

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any and Each Dengue Serotype in Dengue Seropositive Participants at Baseline During Part 5

End point description:

VE is defined as 1 - (λv/λC), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted only once for the "Any Dengue Serotype" category but counted separately for each dengue serotype they belong to.The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). Subjects analysed is the number of participants with seropositive baseline status and with data available for analyses.

End point type	Other pre-specified

End point timeframe:

From Month 14b until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1961	3955		
Units: number of cases				
number (not applicable)				
Any Dengue Serotype	46	33		
DENV-1	12	11		
DENV-2	13	4		
DENV-3	16	15		
DENV-4	6	3		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (Any Dengue Serotype)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	5916
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	65.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	46.4
upper limit	78.1

Statistical analysis title	VE of a TDV Booster Dose (

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	5916
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	56.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	80.7

Statistical analysis title	VE of a TDV Booster Dose
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	5916
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	75.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.2
upper limit	93.9

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

DENV-3

Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	5916
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	54.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.3
upper limit	77.6

Statistical analysis title	VE of a TDV Booster Dose
Statistical analysis description:	
DENV-2	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	5916
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	85.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	54.4
upper limit	95.2

Other pre-specified: VE of a TDV Booster Dose in Preventing Hospitalization Due to Virologically Confirmed Dengue Fever Induced by Any Dengue Serotype During Part 5

End point title	VE of a TDV Booster Dose in Preventing Hospitalization Due to Virologically Confirmed Dengue Fever Induced by Any Dengue Serotype During Part 5

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases requiring hospitalization due to virologically-confirmed dengue fever. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From Month 14b until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2935	5865		
Units: number of cases				
number (not applicable)	13	4		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8800
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	84.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.7
upper limit	95.1

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Severe Dengue Fever Induced by Any Dengue Serotype During Part 5

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Severe Dengue Fever Induced by Any Dengue Serotype During Part 5

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. Severe cases were determined by Adjudication Committee. VE was assessed using the number of severe cases due to virologically-confirmed dengue fever. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From Month 14b until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2935	5865		
Units: number of cases				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Each Dengue Serotype for Parts 4 And 5 Combined

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Each Dengue Serotype for Parts 4 And 5 Combined

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)				
DENV-1	51	32		
DENV-2	49	14		
DENV-3	25	23		
DENV-4	36	15		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigationalproduct as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	69
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.7
upper limit	80

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigationalproduct as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	85.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	74.5
upper limit	92.2

Statistical analysis title	VE of a TDV Booster Dose (DENV-3)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigationalproduct as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	54.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	19.1
upper limit	73.9

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigationalproduct as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	79.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	62.4
upper limit	88.7

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype for Parts 4 And 5 Combined

End point title	VE of a TDV Booster Dose in Preventing Virologically-Confirmed Dengue Fever Induced by Any Dengue Serotype for Parts 4 And 5 Combined

End point description:

The VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases.The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b) until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)	159	84		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	74.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	66.6
upper limit	80.3

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any And Each Dengue Serotype in Dengue Seronegative Participants at Baseline for Parts 4 And 5 Combined

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any And Each Dengue Serotype in Dengue Seronegative Participants at Baseline for Parts 4 And 5 Combined

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted only once for the "Any Dengue Serotype" category but counted separately for each dengue serotype they belong to. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). Subjects analysed is the number of participants with seronegative baseline status and with data available for analyses.

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	986	1928		
Units: number of cases				
number (not applicable)				
Any Dengue Serotype	46	23		
DENV-1	21	10		
DENV-2	10	2		
DENV-3	6	7		
DENV-4	9	4		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (Any Dengue Serotype)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	75.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.3
upper limit	85

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	76.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	50
upper limit	88.9

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)
Statistical analysis description:	
VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.	
Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	78.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	29.7
upper limit	93.3

Statistical analysis title	VE of a TDV Booster Dose (DENV-3)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	37.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-84.9
upper limit	79.2

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	2914
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	89.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.7
upper limit	97.8

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any and Each Dengue Serotype in Dengue Seropositive Participants at Baseline for Parts 4 And 5 Combined

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Dengue Fever Induced by Any and Each Dengue Serotype in Dengue Seropositive Participants at Baseline for Parts 4 And 5 Combined

End point description:

VE is defined as 1 - (λv/λC), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of virologically-confirmed dengue fever cases. Participants are counted only once for the "Any Dengue Serotype" category but counted separately for each dengue serotype they belong to. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). Subjects analysed is the number of participants with seropositive baseline status and with data available for analyses.

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1995	4036		
Units: number of cases				
number (not applicable)				
Any Dengue Serotype	113	61		
DENV-1	30	22		
DENV-2	39	12		
DENV-3	19	16		
DENV-4	27	11		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose (Any Dengue Serotype)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	73.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	64.4
upper limit	80.9

Statistical analysis title	VE of a TDV Booster Dose (DENV-1)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	64.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.8
upper limit	79.3

Statistical analysis title	VE of a TDV Booster Dose (DENV-2)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	84.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	71.1
upper limit	92.1

Statistical analysis title	VE of a TDV Booster Dose (DENV-3)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL

Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	58.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	18.5
upper limit	78.5

Statistical analysis title	VE of a TDV Booster Dose (DENV-4)

Statistical analysis description:

VE and 95% CIs was estimated from Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	6031
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	79.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	59.1
upper limit	89.9

Other pre-specified: VE of a TDV Booster Dose in Preventing Virologically Confirmed Severe Dengue Fever Induced by Any Dengue Serotype for Parts 4 And 5 Combined

End point title	VE of a TDV Booster Dose in Preventing Virologically Confirmed Severe Dengue Fever Induced by Any Dengue Serotype for Parts 4 And 5 Combined

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. Severe cases were determined by Adjudication Committee. VE was assessed using the number of severe cases due to virologically-confirmed dengue fever. The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)	1	0		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	100
Confidence interval	
level	95 %
sides	2-sided
lower limit	-849.4
upper limit	100

Other pre-specified: VE of a TDV Booster Dose in Preventing Hospitalization Due to Virologically Confirmed Dengue Fever Induced by Any Dengue Serotype for Parts 4 And 5 Combined

End point title	VE of a TDV Booster Dose in Preventing Hospitalization Due to Virologically Confirmed Dengue Fever Induced by Any Dengue Serotype for Parts 4 And 5 Combined

End point description:

VE is defined as 1 - (λv/λc), where λv and λc denote the hazard rates for the TDV and placebo arms, respectively. A virologically-confirmed dengue case is defined as febrile illness (defined as temperature ≥38°C on any 2 of 3 consecutive days) or illness clinically suspected to be dengue by the Investigator with a positive serotype-specific RT-PCR. VE was assessed using the number of cases requiring hospitalization due to virologically-confirmed dengue fever. . The PPS-B included all participants in the FAS-B who had no major protocol violations. The FAS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo).

End point type	Other pre-specified

End point timeframe:

From 30 days post-booster vaccination (Day 30b [Month 1b]) until the end of Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2981	5966		
Units: number of cases				
number (not applicable)	37	7		

Statistical analyses

Statistical analysis title	VE of a TDV Booster Dose

Statistical analysis description:

VE and two-sided 95% CIs are estimated from a Cox proportional hazard model with investigational product as a factor, adjusted for age, and stratified by region.

Comparison groups	Placebo v TDV 0.5 mL
Number of subjects included in analysis	8947
Analysis specification	Pre-specified
Analysis type	other
Method	Cox Proportional Hazard Model
Parameter estimate	VE
Point estimate	90.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	78.8
upper limit	95.8

Other pre-specified: Percentage of Participants With Solicited Local Injection Site Adverse Events (AEs) by Severity in the Safety Set-Booster-Immunogenicity Subset During Part 4

End point title	Percentage of Participants With Solicited Local Injection Site Adverse Events (AEs) by Severity in the Safety Set-Booster-Immunogenicity Subset During Part 4

End point description:

Solicited local AEs at injection site are defined as pain, erythema and swelling that occurred within 7 days after each vaccination. The participant/legal guardian recorded the severity of each AE (except erythema and swelling) according to the diary card instruction as none, mild, moderate, or severe. Severity grades for erythema and swelling were derived from the recorded diameters. Percentages were rounded off to the nearest single decimal place. Safety Set-Booster-Immunogenicity Subset included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo) in the safety subset. ‘n’ indicates the number of participants with data available for analyses for the specified category.

End point type	Other pre-specified

End point timeframe:

Days 1b through 7b after booster vaccination in Part 4

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	600	1200		
Units: percentage of participants				
number (not applicable)				
Pain: Mild (n= 595,1182)	12.1	20.1		
Pain: Moderate (n= 595,1182)	3.9	4.6		
Pain: Severe (n= 595,1182)	0.7	1.2		
Erythema: Mild (n= 592,1174)	0.2	1.6		
Erythema: Moderate (n= 592,1174)	0	0		
Erythema: Severe (n= 592,1174)	0	0		
Swelling: Mild (n= 590,1173)	0.5	1.0		
Swelling: Moderate (n= 590,1173)	0	0		
Swelling: Severe (n= 590,1173)	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Participants With Solicited Systemic Adverse Events (AEs) by Severity in the Safety Set-Booster-Immunogenicity Subset During Part 4

End point title	Percentage of Participants With Solicited Systemic Adverse Events (AEs) by Severity in the Safety Set-Booster-Immunogenicity Subset During Part 4

End point description:

Solicited systemic AEs are defined as fever, headache, asthenia, malaise and myalgia that occurred within 14 days after each vaccination. The participant/legal guardian recorded the severity of each AE (except fever) according to the diary card instruction as none, mild, moderate, or severe. Severity grades for fever were derived from the recorded body temperature measurements and presented using the proposed temperature increments published by the Brighton Collaboration. Percentages were rounded off to the nearest single decimal place except the data point where rounding-up may lead to data misinterpretation. Safety Set-Booster-Immunogenicity Subset included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo) in the safety subset. 'n' indicates the number of participants with data available for analyses for the specified category.

End point type	Other pre-specified

End point timeframe:

Days 1b through 14b after booster vaccination in Part 4

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	600	1200		
Units: percentage of participants				
number (not applicable)				
Headache: Mild (n= 594,1184)	8.6	12.3		
Headache: Moderate (n= 594,1184)	4.7	3.7		
Headache: Severe (n= 594,1184)	0.5	1.1		
Asthenia: Mild (n= 594,1184)	7.1	7.2		

Asthenia: Moderate (n= 594,1184)	1.9	2.4		
Asthenia: Severe (n= 594,1184)	0.3	0.7		
Malaise: Mild (n= 593,1184)	7.6	8.6		
Malaise: Moderate (n= 593,1184)	2.0	2.6		
Malaise: Severe (n= 593,1184)	0.5	0.7		
Myalgia: Mild (n= 593,1181)	9.9	11.7		
Myalgia: Moderate (n= 593,1181)	1.5	3.6		
Myalgia: Severe (n= 593,1181)	1.0	0.8		
Fever: 38.0-<38.5 (n= 594,1184)	1.0	1.8		
Fever: 38.5-<39.0 (n= 594,1184)	0.5	1.0		
Fever: 39.0-<39.5 (n= 594,1184)	0.2	0.2		
Fever: 39.5-<40.0 (n= 594,1184)	0	0.3		
Fever: 40.0-<40.5 (n= 594,1184)	0.2	0		
Fever: 40.5-<41.0 (n= 594,1184)	0	0.0873		
Fever: >=41.0 (n= 594,1184)	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Participants With Any Unsolicited Adverse Events (AEs) in the Safety Set-Booster-Immunogenicity Subset During Part 4

End point title	Percentage of Participants With Any Unsolicited Adverse Events (AEs) in the Safety Set-Booster-Immunogenicity Subset During Part 4

End point description:

An AE is defined as any untoward medical occurrence in a clinical investigation participant administered a trial vaccine; it does not necessarily have to have a causal relationship with trial vaccine administration. Unsolicited AEs are any AEs that are not solicited local or systemic AEs, as defined by this study. Percentages were rounded off to the nearest single decimal place.Safety Set-Booster-Immunogenicity Subset included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo) in the safety subset.

End point type	Other pre-specified

End point timeframe:

Days 1b through 28b after booster vaccination in Part 4

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	600	1200		
Units: percentage of participants				
number (not applicable)	1.8	1.8		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Participants With Serious Adverse Events (SAEs) During Parts 4 and 5

End point title	Percentage of Participants With Serious Adverse Events (SAEs) During Parts 4 and 5

End point description:

A serious adverse event (SAE) is any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity, is a congenital anomaly / birth defect or is medically important due to other reasons than the above mentioned criteria. Percentages were rounded off to the nearest single decimal place. In the category 'Part 4 and 5 combined' participants are counted only once even if they experienced events in both Part 4 and Part 5 in order to yield total of unique participants who had SAEs. Safety Set-Booster (SS-B) included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). Number analyzed is the number of participants at risk at the start of the specified analysis period.

End point type	Other pre-specified

End point timeframe:

From Day 1b until the end of Part 4 (Month 13b) and Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2985	5990		
Units: percentage of participants				
number (not applicable)				
Part 4 (n= 2985, 5990)	4.2	2.7		
Part 5 (n= 2939, 5989)	2.5	1.9		
Parts 4 and 5 Combined (n= 2985, 5990)	6.4	4.4		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Participants With Fatal SAEs and SAEs Related to Study Drug During Parts 4 and 5

End point title	Percentage of Participants With Fatal SAEs and SAEs Related to Study Drug During Parts 4 and 5

End point description:

A SAE is any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity, is a congenital anomaly / birth defect or is medically important due to other reasons than above mentioned criteria. Percentages were rounded off to nearest single decimal place except the data points where rounding-up may lead to data misinterpretation. Incategory 'Part 4 and 5 combined' participants are counted only once even if they experienced events in both Part 4 and Part 5 in order to yield total of unique participants who had SAEs. SS-B included all participants 4 to 11 years of age at the time of randomization in the trial (Day 1 [Month 0]) who were included in the PPS and who received the booster dose of trial vaccine (TDV or placebo). 'n' indicates the number of participants at risk at the start of the specified analysis period.

End point type	Other pre-specified

End point timeframe:

From Day 1b until the end of Part 4 (Month 13b) and Part 5 (Month 25b)

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2985	5990		
Units: percentage of participants				
number (not applicable)				
Part 4: Fatal SAEs (n= 2985, 5990)	0.0335	0.0501		
Part 4: SAEs (n= 2985, 5990)	0	0		
Part 5: Fatal SAEs (n= 2939, 5989)	0	0.0509		
Part 5: SAEs (n= 2939, 5989)	0	0		
Parts 4&5 Combined: Fatal SAEs (n= 2985, 5990)	0.0335	0.1		
Parts 4&5 Combined: SAEs (n= 2985, 5990)	0	0		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Seropositivity Rate for Each of The 4 Dengue Serotypes During Parts 4 and 5

End point title	Seropositivity Rate for Each of The 4 Dengue Serotypes During Parts 4 and 5

End point description:

Seropositivity rate, defined as the percentage of participants seropositive, is derived from the titers of dengue-neutralizing antibodies. Seropositivity is defined as a reciprocal neutralizing titer ≥10. The four DENV serotypes are DENV-1, DENV-2, DENV-3 and DENV-4. Percentages were rounded off to the nearest single decimal place except the data points where rounding-up may lead to data misinterpretation. Per-Protocol Set for Immunogenicity-Booster (PPSI-B):all participants in Full Analysis Set for Immunogenicity-Booster (FASI-B) who had no major protocol violations. FASI-B: all participants from FAS-B who were included in booster immunogenicity subset & for whom there is valid pre-booster measurement & at least 1 valid post-booster measurement for immunogenicity assessments. Number analyzed: participants with data available for analyses for the specified category.

End point type	Other pre-specified

End point timeframe:

Pre-booster Vaccination on Day 1b (Month 0b) and post-booster vaccination on Day 30b (Month 1b), Day 180b (Month 6b), Day 395b (Month 13b) and Day 760b (Month 25b) in Parts 4 and 5

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	597	1186		
Units: percentage of participants				
number (not applicable)				
Day 1b: DENV-1 (n= 597, 1186)	70.2	94.4		
Day 1b: DENV-2 (n= 597, 1186)	72.5	99.2		
Day 1b: DENV-3 (n= 597, 1186)	69.0	97.0		
Day 1b: DENV-4 (n= 597, 1186)	67.0	93.4		
Month 1b: DENV-1 (n= 542, 1075)	71.6	99.907		
Month 1b: DENV-2 (n= 542, 1075)	74.5	99.907		
Month 1b: DENV-3 (n= 542, 1075)	72.9	100.0		
Month 1b: DENV-4 (n= 542, 1075)	69.2	99.7		
Month 6b: DENV-1 (n= 562, 1127)	72.8	99.7		
Month 6b: DENV-2 (n= 562, 1127)	75.8	99.8		
Month 6b: DENV-3 (n= 562, 1127)	73.0	99.6		
Month 6b: DENV-4 (n= 562, 1127)	70.3	99.7		
Month 13b: DENV-1 (n= 561, 1122)	74.5	99.911		
Month 13b: DENV-2 (n= 561, 1122)	77.4	99.5		
Month 13b: DENV-3 (n= 561, 1122)	74.9	100.0		
Month 13b: DENV-4 (n= 561, 1122)	72.4	99.8		
Month 25b: DENV-1 (n= 556, 1103)	77.2	99.6		
Month 25b: DENV-2(n= 556, 1103)	78.6	99.8		
Month 25b: DENV-3 (n= 556, 1102)	77.7	99.909		
Month 25b: DENV-4 (n= 556, 1103)	76.3	99.8		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Seropositivity Rate for Multiple Dengue Serotypes During Parts 4 and 5

End point title	Seropositivity Rate for Multiple Dengue Serotypes During Parts 4 and 5

End point description:

Seropositivity rate for multiple Dengue serotypes,defined as percentage of participants seropositive for anyone(monovalent),two(bivalent), three(trivalent), & four(tetravalent) dengue serotypes, as well as at least bivalent(seropositive for ≥2 dengue serotypes) and atleast trivalent (seropositive for ≥3 dengue serotypes), is derived from titers of dengue-neutralizing antibodies. Seropositive response is defined as reciprocal neutralizing titer ≥ 10. The four DENV serotypes are DENV-1, DENV-2,DENV-3,&DENV-4. Percentages were rounded off to nearest single decimal place except the data points where rounding-up may lead to data misinterpretation. PPSI-B:all participants in FASI-B who had no major protocol violations. FASI-B:all participants from FAS-B who were included in booster immunogenicity subset & for whom there is valid pre-booster measurement& atleast 1 valid post-booster measurement for immunogenicity assessments. n:number of participants available for analyses for the category.

End point type	Other pre-specified

End point timeframe:

Pre-booster vaccination on Day 1b (Month 0b) and post-booster vaccination on Day 30b (Month 1b), Day 180b (Month 6b), Day 395b (Month 13b) and Day 760b (Month 25b) in Parts 4 and 5

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	597	1186		
Units: percentage of participants				
number (not applicable)				
Day 1b: Monovalent (n= 597, 1186)	5.7	1.3		
Day 1b: Bivalent (n= 597, 1186)	2.0	3.7		
Day 1b: Trivalent (n= 597, 1186)	2.3	4.6		
Day 1b: Tetravalent (n= 597, 1186)	65.5	90.4		
Day 1b: At Least Bivalent (n= 597, 1186)	69.8	98.7		
Day 1b: At Least Trivalent (n= 597, 1186)	67.8	95.0		
Month 1b: Monovalent (n= 542, 1075)	6.6	0		
Month 1b: Bivalent (n= 542, 1075)	2.0	0		
Month 1b: Trivalent (n= 542, 1075)	3.7	0.5		
Month 1b: Tetravalent (n= 542, 1075)	66.6	99.5		
Month 1b:At Least Bivalent (n= 542, 1075)	72.3	100.0		
Month 1b:At Least Trivalent (n= 542, 1075)	70.3	100.0		
Month 6b:Monovalent (n= 562, 1127)	6.8	0.0887		
Month 6b: Bivalent (n= 562, 1127)	2.5	0.0887		
Month 6b: Trivalent (n= 562, 1127)	3.2	0.6		
Month 6b: Tetravalent (n= 562, 1126)	67.6	99.2		
Month 6b:At Least Bivalent (n= 562, 1127)	73.3	99.911		
Month 6b:At Least Trivalent (n= 562, 1127)	70.8	99.8		
Month 13b: Monovalent (n= 561, 1122)	6.6	0		
Month 13b: Bivalent (n= 561, 1122)	2.1	0		
Month 13b: Trivalent (n= 561, 1122)	2.7	0.8		
Month 13b: Tetravalent (n= 561, 1122)	70.1	99.2		
Month 13b: At Least Bivalent (n= 561, 1122)	74.9	100.0		
Month 13b: At Least Trivalent (n= 561, 1122)	72.7	100.0		
Month 25b: Monovalent (n= 556, 1103)	3.4	0		
Month 25b: Bivalent (n= 556, 1103)	1.8	0.0907		
Month 25b: Trivalent (n= 556, 1103)	1.6	0.4		
Month 25b: Tetravalent (n= 556, 1102)	74.5	99.5		
Month 25b: At Least Bivalent (n= 556, 1103)	77.9	99.909		
Month 25b: At Least Trivalent (n= 556, 1103)	76.1	99.8		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Geometric Mean Titers (GMTs) of Neutralizing Antibodies for Each of the Four Dengue Serotypes During Parts 4 And 5

End point title	Geometric Mean Titers (GMTs) of Neutralizing Antibodies for Each of the Four Dengue Serotypes During Parts 4 And 5

End point description:

GMTs of neutralizing antibodies were measured via MNT50. The four DENV serotypes are DENV-1, DENV-2, DENV-3 and DENV-4.

End point type	Other pre-specified

End point timeframe:

Pre-booster Vaccination on Day 1b (Month 0b) and post-booster vaccination on Day 30b (Month 1b), Day 180b (Month 6b), Day 395b (Month 13b) and Day 760b (Month 25b) in Parts 4 and 5

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	597	1186		
Units: titres				
geometric mean (confidence interval 95%)				
Day 1b: DENV-1 (n= 597, 1186)	172.7 (137.8 to 216.5)	374.7 (332.7 to 422.1)		
Day 1b: DENV-2 (n= 597, 1186)	164.5 (133.2 to 203.2)	609.4 (558.6 to 664.7)		
Day 1b: DENV-3 (n= 597, 1186)	129.4 (105.0 to 159.4)	305.2 (274.6 to 339.3)		
Day 1b: DENV-4 (n= 597, 1186)	81.5 (67.8 to 98.1)	172.9 (156.1 to 191.4)		
Month 1b: DENV-1 (n= 542, 1075)	179.8 (142.4 to 227.0)	1493.8 (1383.2 to 1613.3)		
Month 1b: DENV-2 (n= 542, 1075)	174.8 (140.5 to 217.6)	1611.5 (1492.1 to 1740.4)		
Month 1b: DENV-3 (n= 542, 1075)	159.9 (128.4 to 199.0)	1546.6 (1450.0 to 1649.6)		
Month 1b: DENV-4 (n= 542, 1075)	87.3 (72.0 to 105.9)	793.8 (742.5 to 848.7)		
Month 6b: DENV-1 (n= 562, 1127)	191.5 (152.2 to 241.0)	1000.9 (916.8 to 1092.7)		
Month 6b: DENV-2 (n= 562, 1127)	208.0 (167.6 to 258.0)	1167.2 (1080.8 to 1260.5)		
Month 6b: DENV-3 (n= 562, 1127)	156.0 (126.1 to 192.9)	851.0 (788.9 to 917.9)		
Month 6b: DENV-4 (n= 562, 1127)	86.4 (71.9 to 103.9)	457.6 (427.4 to 490.0)		
Month 13b: DENV-1 (n= 561, 1122)	259.3 (204.8 to 328.4)	949.1 (862.2 to 1044.7)		
Month 13b: DENV-2 (n= 561, 1122)	248.9 (199.4 to 310.6)	1003.2 (920.1 to 1093.9)		
Month 13b: DENV-3 (n= 561, 1122)	199.1 (159.9 to 248.0)	804.1 (739.2 to 874.8)		
Month 13b: DENV-4(n= 561, 1122)	115.0 (94.4 to 140.0)	433.1 (401.2 to 467.6)		

Month 25b: DENV-1 (n= 556, 1103)	293.8 (233.1 to 370.3)	865.6 (782.7 to 957.2)		
Month 25b: DENV-2 (n= 556, 1103)	278.5 (224.3 to 345.8)	951.6 (873.0 to 1037.2)		
Month 25b: DENV-3 (n= 556, 1102)	229.7 (185.5 to 284.3)	688.3 (632.2 to 749.3)		
Month 25b: DENV-4 (n= 556, 1103)	129.2 (106.8 to 156.3)	387.9 (358.6 to 419.6)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Geometric Mean Ratio (GMR) of Neutralizing Antibodies for Each Dengue Serotype

End point title	Geometric Mean Ratio (GMR) of Neutralizing Antibodies for Each Dengue Serotype

End point description:

The GMR is the geometric mean of the ratio of the two visits being compared. PPSI-B: all participants in FASI-B who had no major protocol violations. FASI-B: all participants from FAS-B who were included in booster immunogenicity subset & for whom there is valid pre-booster measurement & at least 1 valid post-booster measurement for immunogenicity assessments. Subjects analysed: number of participants with data available for analyses. n: number of participants with data available for analyses for specified category.

End point type	Other pre-specified

End point timeframe:

Pre-booster Vaccination on Day 1b (Month 0b) versus post-booster vaccination on Day 30b (Month 1b) in Part 4

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	396	1067		
Units: unitless ratio				
geometric mean (confidence interval 95%)				
DENV-1 (n= 383, 1016)	0.9 (0.8 to 1.0)	3.1 (2.8 to 3.4)		
DENV-2 (n= 396, 1067)	0.9 (0.9 to 1.0)	2.4 (2.3 to 2.6)		
DENV-3 (n= 375, 1042)	1.1 (1.0 to 1.2)	4.3 (3.9 to 4.7)		
DENV-4 (n= 365, 1008)	0.9 (0.9 to 1.0)	3.5 (3.2 to 3.9)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GMR of Neutralizing Antibodies for Each Dengue Serotype: Part 4

End point title	GMR of Neutralizing Antibodies for Each Dengue Serotype: Part 4

End point description:

The GMR is the geometric mean of the ratio of the two visits being compared. PPSI-B: all participants in FASI-B who had no major protocol violations. FASI-B: all participants from FAS-B who were included in booster immunogenicity subset & for whom there is valid pre-booster measurement & at least 1 valid post-booster measurement for immunogenicity assessments. Subjects analysed: number of participants with data available for analyses. n: number of participants with data available for analyses for specified category.

End point type	Other pre-specified

End point timeframe:

Pre-booster Vaccination on Day 1b (Month 0b) versus post-booster vaccination on Day 180b (Month 6b) in Part 4

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	408	1120		
Units: unitless ratio				
geometric mean (confidence interval 95%)				
DENV-1 (n= 396, 1064)	1.0 (0.9 to 1.1)	2.2 (2.0 to 2.4)		
DENV-2 (n= 408, 1120)	1.1 (1.0 to 1.3)	1.8 (1.7 to 2.0)		
DENV-3 (n= 389, 1089)	1.0 (0.9 to 1.1)	2.5 (2.3 to 2.7)		
DENV-4 (n= 377, 1052)	0.9 (0.8 to 1.0)	2.1 (2.0 to 2.3)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GMR of Neutralizing Antibodies for Each Dengue Serotype :Part 4

End point title	GMR of Neutralizing Antibodies for Each Dengue Serotype :Part 4

End point description:

The geometric mean ratio is the geometric mean of the ratio of the two visits being compared. PPSI-B: all participants in FASI-B who had no major protocol violations. FASI-B: all participants from FAS-B who were included in booster immunogenicity subset & for whom there is valid pre-booster measurement & at least 1 valid post-booster measurement for immunogenicity assessments. Subjects analysed: number of participants with data available for analyses. n: number of participants with data available for analyses for specified category.

End point type	Other pre-specified

End point timeframe:

Pre-booster Vaccination on Day 1b (Month 0b) versus post-booster vaccination on Day 395b (Month 13b) in Part 4

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	408	1114		
Units: unitless ratio				
geometric mean (confidence interval 95%)				
DENV-1 (n= 395, 1060)	1.3 (1.1 to 1.5)	2.1 (1.9 to 2.3)		
DENV-2 (n= 408, 1114)	1.3 (1.1 to 1.5)	1.6 (1.5 to 1.7)		
DENV-3 (n= 389, 1088)	1.3 (1.1 to 1.5)	2.4 (2.2 to 2.6)		
DENV-4 (n= 377, 1052)	1.3 (1.1 to 1.4)	2.0 (1.9 to 2.2)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: GMR of Neutralizing Antibodies for Each Dengue Serotype

End point title	GMR of Neutralizing Antibodies for Each Dengue Serotype

End point description:

The geometric mean ratio is the geometric mean of the ratio of the two visits being compared. PPSI-B: all participants in FASI-B who had no major protocol violations. FASI-B: all participants from FAS-B who were included in booster immunogenicity subset & for whom there is valid pre-booster measurement & at least 1 valid post-booster measurement for immunogenicity assessments. Subjects analysed: number of participants with data available for analyses. n: number of participants with data available for analyses for specified category.

End point type	Other pre-specified

End point timeframe:

Pre-booster Vaccination on Day 1b (Month 0b) versus post-booster vaccination on Day 720b (Month 25b) in Part 5

End point values	Placebo	TDV 0.5 mL		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	398	1095		
Units: unitless ratio				
geometric mean (confidence interval 95%)				
DENV-1 (n= 384,1043)	1.3 (1.2 to 1.5)	2.0 (1.9 to 2.2)		
DENV-2 (n= 398,1043)	1.3 (1.1 to 1.5)	1.6 (1.5 to 1.7)		
DENV-3 (n= 379,1068)	1.4 (1.2 to 1.6)	2.1 (1.9 to 2.3)		
DENV-4 (n= 367,1028)	1.3 (1.1 to 1.5)	1.9 (1.8 to 2.1)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Deaths & SAEs:Parts1+2:Day1 to end of Part2 (approx.21 months);Part3:approx.3years; Parts4+5:from booster vaccination (Vc) (Day1b) until end of Part5 [approx.25 months];Other AEs:Part1:up to 28 days post 1st/2nd V;Part4:up to 28 days post booster V

Adverse event reporting additional description:

As pre-specified in protocol, AEs are reported separately for Placebo and TDV arms of each Part. For Part 1-3: Safety Set. For Part 4-5: Safety Set-Booster.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Placebo (Part 1)

Reporting group description:

Participants received placebo-matching TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study. Participants eligible for Booster Phase received placebo matching TDV, SC injection on Day 1b (Month 0b) in Part 4 of the study based on the randomization code applied in Part 1 of the study.

Reporting group title	Placebo (Part 2)

Reporting group description:

Participants went through extended follow-up period for six months up to Month 21 in Part 2 of the study.

Reporting group title	TDV (Part 2)

Reporting group description:

Participants went through extended follow-up period for six months up to Month 21 in Part 2 of the study.

Reporting group title	TDV (Part 5)

Reporting group description:

Participants went through extended follow-up period for 1 year up to Month 25b in Part 5 of the study.

Reporting group title	TDV (Part 3)

Reporting group description:

Participants eligible for Booster Phase received placebo matching TDV, SC injection, based on the randomization on Day 1 (Month 0) in Part 4 of the study.

Reporting group title	Placebo (Part 4)

Reporting group description:

Participants eligible for Booster Phase received placebo matching TDV, SC injection, based on the randomization on Day 1 (Month 0) in Part 4 of the study.

Reporting group title	TDV (Part 4)

Reporting group description:

Participants eligible for Booster Phase received TDV, SC injection, based on the randomization on Day 1 (Month 0) in Part 4 of the study.

Reporting group title	Placebo (Part 5)

Reporting group description:

Participants went through extended follow-up period for 1 year up to Month 25b in Part 5 of the study.

Reporting group title	TDV (Part 1)

Reporting group description:

Participants received TDV, 0.5 mL, SC injection on Day 1 (Month 0) and Day 90 (Month 3) in Part 1 of the study.

Reporting group title	Placebo (Part 3)

Reporting group description:

Participants went through long-term follow-up (3 years) to evaluate the safety.

Serious adverse events	Placebo (Part 1)	Placebo (Part 2)	TDV (Part 2)
Total subjects affected by serious adverse events			
subjects affected / exposed	256 / 6687 (3.83%)	82 / 6519 (1.26%)	152 / 13033 (1.17%)
number of deaths (all causes)	8	7	18
number of deaths resulting from adverse events	1	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolar rhabdomyosarcoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ovarian tumour			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign hydatidiform mole			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Desmoplastic small round cell tumour			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous T-cell lymphoma			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ependymoma malignant			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of breast			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory myofibroblastic tumour			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian germ cell endodermal sinus tumour stage IV			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondroma			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcerated haemangioma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kawasaki's disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarteritis nodosa			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subgaleal haematoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			

Abortion			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion complete			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion missed			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion incomplete			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous incomplete			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anembryonic gestation			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
False labour			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eclampsia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
High risk pregnancy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperemesis gravidarum			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labour complication			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyhydramnios			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental insufficiency			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature delivery			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic delivery			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord prolapse			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unstable foetal lie			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hanging			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drowning			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organ failure			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serositis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod bite			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	2 / 6687 (0.03%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food allergy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type I hypersensitivity			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
High risk sexual behaviour			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance use			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sexual abuse			
subjects affected / exposed	3 / 6687 (0.04%)	0 / 6519 (0.00%)	4 / 13033 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Physical assault			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Victim of crime			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Victim of sexual abuse			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balanoposthitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal uterine bleeding			

subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovulation pain			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular torsion			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal pain			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile adhesion			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval haematoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			

subjects affected / exposed	2 / 6687 (0.03%)	1 / 6519 (0.02%)	7 / 13033 (0.05%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			
subjects affected / exposed	3 / 6687 (0.04%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus pleurisy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus polyp			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aggression			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Antisocial behaviour			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Behaviour disorder			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disruptive mood dysregulation disorder			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug abuse			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional self-injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mania			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oppositional defiant disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric symptom			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Self-destructive behaviour			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance use disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal behaviour			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device extrusion			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			

Cholangitis sclerosing			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatosplenomegaly			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic dysfunction-associated steatohepatitis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
False positive investigation result			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product by child			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident at work			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	4 / 6687 (0.06%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod bite			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod sting			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Avulsion fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness traumatic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical burn of oral cavity			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrical burn			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electric shock			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electric injury			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epidural haemorrhage			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure to communicable disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	2 / 6687 (0.03%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	3 / 6687 (0.04%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	1 / 6687 (0.01%)	2 / 6519 (0.03%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ilium fracture			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	3 / 6687 (0.04%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic rupture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	3 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip injury			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver contusion			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open globe injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating abdominal trauma			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural discharge			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	7 / 6687 (0.10%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 7	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Shunt malfunction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin injury			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snake bite			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury thoracic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sports injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	2 / 6687 (0.03%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			

subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic lung injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venom poisoning			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous malformation			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriovenous malformation haemorrhagic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular arteriovenous malformation			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Congenital cystic kidney disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermoid cyst			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Familial periodic paralysis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular dystrophy			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalassaemia alpha			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic heart disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aqueductal stenosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bell's palsy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain hypoxia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous thrombosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplegia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic generalised epilepsy			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic headache			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychogenic seizure			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serotonin syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status migrainosus			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			

subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of pregnancy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deficiency anaemia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric lymphadenitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amaurosis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis allergic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal opacity			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refraction disorder			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orbital myositis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acid peptic disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphthous ulcer			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	2 / 6687 (0.03%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	3 / 6687 (0.04%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 6687 (0.01%)	3 / 6519 (0.05%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoid hyperplasia of intestine			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric cyst			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Henoch-Schonlein purpura			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema annulare			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen planus			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive nephropathy			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis acute			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis chronic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis proliferative			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis rapidly progressive			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritic syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus nephritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post infection glomerulonephritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post streptococcal glomerulonephritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelocaliectasis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral caruncle			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder rupture			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cushing's syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphysiolysis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis of jaw			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity contracture			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Juvenile idiopathic arthritis			

subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee deformity			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle fatigue			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic fever			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion infected			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of external ear			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess soft tissue			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	1 / 6687 (0.01%)	2 / 6519 (0.03%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amniotic cavity infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebic dysentery			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	14 / 6687 (0.21%)	6 / 6519 (0.09%)	14 / 13033 (0.11%)
occurrences causally related to treatment / all	0 / 14	0 / 6	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	3 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arboviral infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascariasis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial vaginosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteriuria			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cellulitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burkholderia pseudomallei infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burn infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	3 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chikungunya virus infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholera			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	52 / 6687 (0.78%)	10 / 6519 (0.15%)	9 / 13033 (0.07%)
occurrences causally related to treatment / all	1 / 52	0 / 10	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue haemorrhagic fever			
subjects affected / exposed	19 / 6687 (0.28%)	6 / 6519 (0.09%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	1 / 19	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis infected			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema infectiosum			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection gonococcal			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	8 / 6687 (0.12%)	2 / 6519 (0.03%)	7 / 13033 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis shigella			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giardiasis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis viral			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex encephalitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impetigo			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of asthma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	7 / 6687 (0.10%)	5 / 6519 (0.08%)	6 / 13033 (0.05%)
occurrences causally related to treatment / all	0 / 7	0 / 5	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective myositis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leptospirosis			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			

subjects affected / exposed	3 / 6687 (0.04%)	1 / 6519 (0.02%)	3 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph gland infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node tuberculosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis bacterial			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis tuberculous			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	3 / 6687 (0.04%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstetric infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parasite allergy			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranasal sinus abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parasitic gastroenteritis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	3 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis bacterial			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	8 / 6687 (0.12%)	7 / 6519 (0.11%)	6 / 13033 (0.05%)
occurrences causally related to treatment / all	0 / 8	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal disease			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum sepsis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Puerperal infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustule			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			

subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rickettsiosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 sepsis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scarlet fever			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic phlebitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis bacterial			
subjects affected / exposed	0 / 6687 (0.00%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syphilis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 6687 (0.01%)	1 / 6519 (0.02%)	2 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea capitis			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis bacterial			

subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	2 / 6687 (0.03%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	5 / 6687 (0.07%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethritis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	2 / 6687 (0.03%)	1 / 6519 (0.02%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal infection			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	5 / 6687 (0.07%)	2 / 6519 (0.03%)	4 / 13033 (0.03%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	19 / 6687 (0.28%)	4 / 6519 (0.06%)	3 / 13033 (0.02%)
occurrences causally related to treatment / all	0 / 20	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pharyngitis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	1 / 13033 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic syndrome			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 6687 (0.00%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 6687 (0.01%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	TDV (Part 5)	TDV (Part 3)	Placebo (Part 4)
Total subjects affected by serious			

adverse events			
subjects affected / exposed	109 / 5889 (1.85%)	666 / 12961 (5.14%)	126 / 2985 (4.22%)
number of deaths (all causes)	3	17	1
number of deaths resulting from adverse events	3	11	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolar rhabdomyosarcoma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ovarian tumour			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign hydatidiform mole			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Desmoplastic small round cell tumour			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous T-cell lymphoma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ependymoma malignant			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of breast			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory myofibroblastic tumour			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian germ cell endodermal sinus tumour stage IV			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondroma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcerated haemangioma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kawasaki's disease			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarteritis nodosa			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subgaleal haematoma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abortion complete			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion missed			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion incomplete			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	0 / 5889 (0.00%)	6 / 12961 (0.05%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous incomplete			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anembryonic gestation			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
False labour			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eclampsia			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
High risk pregnancy			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperemesis gravidarum			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labour complication			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyhydramnios			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental insufficiency			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage			

subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 5889 (0.00%)	9 / 12961 (0.07%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature delivery			
subjects affected / exposed	0 / 5889 (0.00%)	8 / 12961 (0.06%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	1 / 5889 (0.02%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	1 / 5889 (0.02%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic delivery			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord prolapse			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unstable foetal lie			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hanging			
subjects affected / exposed	1 / 5889 (0.02%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Drowning			

subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Influenza like illness			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Organ failure			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serositis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food allergy			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type I hypersensitivity			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
High risk sexual behaviour			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance use			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sexual abuse			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Physical assault			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Victim of crime			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Victim of sexual abuse			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balanoposthitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal uterine bleeding			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovulation pain			

subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular torsion			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal pain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile adhesion			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval haematoma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	2 / 5889 (0.03%)	5 / 12961 (0.04%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			

subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus pleurisy			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus polyp			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aggression			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Antisocial behaviour			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Behaviour disorder			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 5889 (0.00%)	4 / 12961 (0.03%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 0
Depression			
subjects affected / exposed	0 / 5889 (0.00%)	7 / 12961 (0.05%)	2 / 2985 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug abuse			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional self-injury			
subjects affected / exposed	2 / 5889 (0.03%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mania			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mixed anxiety and depressive disorder			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oppositional defiant disorder			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric symptom			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Self-destructive behaviour			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance use disorder			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal behaviour			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 5889 (0.02%)	5 / 12961 (0.04%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device extrusion			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis sclerosing			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatosplenomegaly			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic dysfunction-associated steatohepatitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
False positive investigation result			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 5889 (0.00%)	4 / 12961 (0.03%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product by child			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident at work			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			

subjects affected / exposed	1 / 5889 (0.02%)	10 / 12961 (0.08%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod bite			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod sting			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Avulsion fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back injury			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness traumatic			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical burn of oral cavity			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	1 / 5889 (0.02%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Craniofacial fracture			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrical burn			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electric shock			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electric injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epidural haemorrhage			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure to communicable disease			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 5889 (0.00%)	4 / 12961 (0.03%)	3 / 2985 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	2 / 5889 (0.03%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	1 / 5889 (0.02%)	9 / 12961 (0.07%)	4 / 2985 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			

subjects affected / exposed	1 / 5889 (0.02%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Head injury			
subjects affected / exposed	1 / 5889 (0.02%)	3 / 12961 (0.02%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 1
Hand fracture			
subjects affected / exposed	1 / 5889 (0.02%)	5 / 12961 (0.04%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ilium fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 5889 (0.00%)	7 / 12961 (0.05%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic rupture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	2 / 2985 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 5889 (0.02%)	4 / 12961 (0.03%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			

subjects affected / exposed	1 / 5889 (0.02%)	4 / 12961 (0.03%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver contusion			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 5889 (0.00%)	4 / 12961 (0.03%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck injury			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open globe injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic injury			

subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating abdominal trauma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural discharge			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			

subjects affected / exposed	2 / 5889 (0.03%)	12 / 12961 (0.09%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 2	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	6 / 5889 (0.10%)	9 / 12961 (0.07%)	3 / 2985 (0.10%)
occurrences causally related to treatment / all	0 / 6	0 / 9	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Shunt malfunction			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snake bite			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury thoracic			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sports injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular injury			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 5889 (0.00%)	5 / 12961 (0.04%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic lung injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venom poisoning			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous malformation			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriovenous malformation haemorrhagic			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular arteriovenous malformation			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cystic kidney disease			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cryptorchism			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermoid cyst			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Familial periodic paralysis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular dystrophy			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalassaemia alpha			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic heart disease			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aqueductal stenosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bell's palsy			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain hypoxia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous thrombosis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplegia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic generalised epilepsy			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic headache			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychogenic seizure			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured cerebral aneurysm			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serotonin syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status migrainosus			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 5889 (0.02%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of pregnancy			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deficiency anaemia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric lymphadenitis			
subjects affected / exposed	0 / 5889 (0.00%)	4 / 12961 (0.03%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amaurosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis allergic			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal opacity			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refraction disorder			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orbital myositis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 5889 (0.02%)	4 / 12961 (0.03%)	2 / 2985 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acid peptic disease			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphthous ulcer			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 5889 (0.02%)	5 / 12961 (0.04%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			

subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 5889 (0.02%)	6 / 12961 (0.05%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoid hyperplasia of intestine			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric cyst			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema annulare			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 5889 (0.02%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			

subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen planus			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive nephropathy			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis acute			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis chronic			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis proliferative			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis rapidly progressive			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritic syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus nephritis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post infection glomerulonephritis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post streptococcal glomerulonephritis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelocaliectasis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral caruncle			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder rupture			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cushing's syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Back pain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphysiolysis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis of jaw			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity contracture			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Juvenile idiopathic arthritis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee deformity			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle fatigue			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic fever			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion infected			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	2 / 5889 (0.03%)	7 / 12961 (0.05%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of external ear			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess soft tissue			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amniotic cavity infection			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebic dysentery			
subjects affected / exposed	0 / 5889 (0.00%)	6 / 12961 (0.05%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	12 / 5889 (0.20%)	60 / 12961 (0.46%)	5 / 2985 (0.17%)
occurrences causally related to treatment / all	0 / 12	0 / 60	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			

subjects affected / exposed	2 / 5889 (0.03%)	7 / 12961 (0.05%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arboviral infection			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascariasis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial vaginosis			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteriuria			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's abscess			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cellulitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burkholderia pseudomallei infection			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burn infection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 5889 (0.02%)	69 / 12961 (0.53%)	39 / 2985 (1.31%)
occurrences causally related to treatment / all	0 / 1	0 / 69	0 / 40
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 5889 (0.00%)	15 / 12961 (0.12%)	2 / 2985 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 15	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 5889 (0.00%)	7 / 12961 (0.05%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chikungunya virus infection			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholera			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			
subjects affected / exposed	1 / 5889 (0.02%)	12 / 12961 (0.09%)	4 / 2985 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 12	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	9 / 5889 (0.15%)	56 / 12961 (0.43%)	32 / 2985 (1.07%)
occurrences causally related to treatment / all	0 / 9	0 / 56	0 / 32
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue haemorrhagic fever			
subjects affected / exposed	0 / 5889 (0.00%)	9 / 12961 (0.07%)	4 / 2985 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis infected			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema infectiosum			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection gonococcal			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	4 / 5889 (0.07%)	18 / 12961 (0.14%)	2 / 2985 (0.07%)
occurrences causally related to treatment / all	0 / 4	0 / 18	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis shigella			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 5889 (0.02%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giardiasis			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis viral			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex encephalitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impetigo			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			

subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of asthma			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	3 / 5889 (0.05%)	12 / 12961 (0.09%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 3	0 / 12	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective myositis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint abscess			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leptospirosis			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph gland infection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node tuberculosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis bacterial			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis tuberculous			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle abscess			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstetric infection			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parasite allergy			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranasal sinus abscess			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parasitic gastroenteritis			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital abscess			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	2 / 5889 (0.03%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis bacterial			

subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 5889 (0.05%)	20 / 12961 (0.15%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 20	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal disease			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 5889 (0.00%)	4 / 12961 (0.03%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum sepsis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Puerperal infection			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 5889 (0.02%)	4 / 12961 (0.03%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustule			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			

subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	2 / 2985 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rickettsiosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 sepsis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scarlet fever			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic phlebitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis bacterial			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			

subjects affected / exposed	0 / 5889 (0.00%)	4 / 12961 (0.03%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syphilis			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 5889 (0.02%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea capitis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis bacterial			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection bacterial			

subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	2 / 5889 (0.03%)	9 / 12961 (0.07%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 9	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethritis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal infection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	3 / 5889 (0.05%)	20 / 12961 (0.15%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 24	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	3 / 5889 (0.05%)	16 / 12961 (0.12%)	3 / 2985 (0.10%)
occurrences causally related to treatment / all	0 / 3	0 / 16	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pharyngitis			
subjects affected / exposed	1 / 5889 (0.02%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 5889 (0.02%)	3 / 12961 (0.02%)	1 / 2985 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic syndrome			
subjects affected / exposed	0 / 5889 (0.00%)	1 / 12961 (0.01%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 5889 (0.00%)	2 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 5889 (0.00%)	3 / 12961 (0.02%)	0 / 2985 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	TDV (Part 4)	Placebo (Part 5)	TDV (Part 1)
Total subjects affected by serious adverse events			
subjects affected / exposed	161 / 5990 (2.69%)	73 / 2939 (2.48%)	414 / 13380 (3.09%)
number of deaths (all causes)	6	0	22
number of deaths resulting from adverse events	3	0	4

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alveolar rhabdomyosarcoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign ovarian tumour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign hydatidiform mole			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Desmoplastic small round cell tumour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cutaneous T-cell lymphoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carcinoma in situ			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ependymoma malignant			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Fibroadenoma of breast			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory myofibroblastic tumour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukaemia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian germ cell endodermal sinus tumour stage IV			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondroma			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulcerated haemangioma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kawasaki's disease			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyarteritis nodosa			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subgaleal haematoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion complete			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abortion missed			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion incomplete			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	1 / 5990 (0.02%)	3 / 2939 (0.10%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous incomplete			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion threatened			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anembryonic gestation			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
False labour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eclampsia			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
High risk pregnancy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperemesis gravidarum			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labour complication			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyhydramnios			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental insufficiency			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature delivery			
subjects affected / exposed	1 / 5990 (0.02%)	2 / 2939 (0.07%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured ectopic pregnancy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic delivery			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord prolapse			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unstable foetal lie			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hanging			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drowning			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza like illness			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organ failure			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	5 / 13380 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serositis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Allergy to arthropod bite			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic shock			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food allergy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug hypersensitivity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type I hypersensitivity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
High risk sexual behaviour			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance use			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sexual abuse			

subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Physical assault			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Victim of crime			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Victim of sexual abuse			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Balanoposthitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abnormal uterine bleeding			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovulation pain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular torsion			

subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal pain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile adhesion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulval haematoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenoidal hypertrophy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	3 / 5990 (0.05%)	0 / 2939 (0.00%)	7 / 13380 (0.05%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthmatic crisis			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus pleurisy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus polyp			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Acute psychosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aggression			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Antisocial behaviour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety disorder			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Behaviour disorder			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disruptive mood dysregulation disorder			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug abuse			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional self-injury			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	1 / 5990 (0.02%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mania			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oppositional defiant disorder			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric symptom			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Self-destructive behaviour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance use disorder			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal behaviour			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 5990 (0.02%)	2 / 2939 (0.07%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device extrusion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device malfunction			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholangitis sclerosing			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic steatosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatosplenomegaly			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic dysfunction-associated steatohepatitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal hypertension			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
False positive investigation result			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Red blood cell sedimentation rate increased			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental exposure to product by child			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident at work			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	2 / 5990 (0.03%)	2 / 2939 (0.07%)	8 / 13380 (0.06%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod bite			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ankle fracture			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropod sting			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Avulsion fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blindness traumatic			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burns second degree			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chemical burn of oral cavity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			

subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 5990 (0.00%)	2 / 2939 (0.07%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Craniofacial fracture			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrical burn			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electric shock			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electric injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epidural haemorrhage			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural haematoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure to communicable disease			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphyseal injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyelid injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 5990 (0.02%)	1 / 2939 (0.03%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibula fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	1 / 5990 (0.02%)	2 / 2939 (0.07%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	3 / 5990 (0.05%)	2 / 2939 (0.07%)	8 / 13380 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body in gastrointestinal tract			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured coccyx			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Head injury			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	4 / 13380 (0.03%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hand fracture			

subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ilium fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	10 / 13380 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic rupture			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional overdose			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament injury			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb crushing injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb traumatic amputation			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	1 / 5990 (0.02%)	1 / 2939 (0.03%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver contusion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle strain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open globe injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overdose			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penetrating abdominal trauma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural discharge			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative adhesion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	3 / 5990 (0.05%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			

subjects affected / exposed	3 / 5990 (0.05%)	3 / 2939 (0.10%)	8 / 13380 (0.06%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt malfunction			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin injury			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fractured base			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Snake bite			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord injury thoracic			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic rupture			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sports injury			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Testicular injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	4 / 5990 (0.07%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haematoma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 5990 (0.02%)	2 / 2939 (0.07%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic intracranial haemorrhage			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic liver injury			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic lung injury			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulna fracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venom poisoning			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist fracture			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous malformation			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral arteriovenous malformation haemorrhagic			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular arteriovenous malformation			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Congenital cystic kidney disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermoid cyst			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Familial periodic paralysis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular dystrophy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thalassaemia alpha			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve incompetence			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arrhythmia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic heart disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus node dysfunction			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aqueductal stenosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bell's palsy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain hypoxia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebellar infarction			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous thrombosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diplegia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	4 / 13380 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Guillain-Barre syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocephalus			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic generalised epilepsy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post-traumatic headache			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychogenic seizure			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ruptured cerebral aneurysm			

subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Serotonin syndrome			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Simple partial seizures			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status migrainosus			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	2 / 5990 (0.03%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tension headache			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia of pregnancy			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deficiency anaemia			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric lymphadenitis			

subjects affected / exposed	0 / 5990 (0.00%)	2 / 2939 (0.07%)	5 / 13380 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic thrombocytopenic purpura			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenic purpura			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amaurosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis allergic			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corneal opacity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myopia			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Refraction disorder			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orbital myositis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal haemorrhage			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 5990 (0.02%)	1 / 2939 (0.03%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acid peptic disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphthous ulcer			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	6 / 13380 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis erosive			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic erosive gastritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus paralytic			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine polyp			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoid hyperplasia of intestine			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mechanical ileus			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric cyst			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic pseudocyst			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peptic ulcer			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal polyp			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema annulare			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	4 / 13380 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lichen planus			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkeratosis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
End stage renal disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus urinary			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive nephropathy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis acute			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis chronic			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis proliferative			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis rapidly progressive			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephritic syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lupus nephritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IgA nephropathy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post infection glomerulonephritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post streptococcal glomerulonephritis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	5 / 13380 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelocaliectasis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral caruncle			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary bladder rupture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Goitre			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cushing's syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphysiolysis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Costochondritis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis of jaw			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity contracture			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greater trochanteric pain syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Juvenile idiopathic arthritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee deformity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle fatigue			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neck pain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rheumatic fever			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic lupus erythematosus			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess jaw			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion infected			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	5 / 13380 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of external ear			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess soft tissue			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acarodermatitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amniotic cavity infection			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebic dysentery			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amoebiasis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	7 / 5990 (0.12%)	4 / 2939 (0.14%)	30 / 13380 (0.22%)
occurrences causally related to treatment / all	0 / 7	0 / 4	0 / 30
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis perforated			
subjects affected / exposed	3 / 5990 (0.05%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arboviral infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascariasis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial sepsis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial vaginosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteriuria			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bartholin's abscess			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	4 / 13380 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cellulitis			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis viral			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bullous impetigo			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burkholderia pseudomallei infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burn infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	65 / 5990 (1.09%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 68	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	3 / 5990 (0.05%)	1 / 2939 (0.03%)	10 / 13380 (0.07%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chikungunya virus infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholera			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronavirus infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Complicated appendicitis			

subjects affected / exposed	2 / 5990 (0.03%)	0 / 2939 (0.00%)	6 / 13380 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	7 / 5990 (0.12%)	17 / 2939 (0.58%)	13 / 13380 (0.10%)
occurrences causally related to treatment / all	0 / 7	0 / 17	1 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue haemorrhagic fever			
subjects affected / exposed	0 / 5990 (0.00%)	3 / 2939 (0.10%)	4 / 13380 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis infected			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis infectious			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysentery			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema infectiosum			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia sepsis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection gonococcal			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal peritonitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Folliculitis			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gangrene			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	29 / 13380 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacterial			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis shigella			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal bacterial infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giardiasis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis A			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis viral			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex encephalitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected bite			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impetigo			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective exacerbation of asthma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	14 / 13380 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective myositis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leptospirosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 5990 (0.02%)	1 / 2939 (0.03%)	10 / 13380 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ludwig angina			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph gland infection			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph node tuberculosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis bacterial			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis tuberculous			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstetric infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral herpes			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			

subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis externa			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parasite allergy			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranasal sinus abscess			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parasitic gastroenteritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital abscess			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis bacterial			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	2 / 5990 (0.03%)	0 / 2939 (0.00%)	10 / 13380 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal disease			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomembranous colitis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum sepsis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Puerperal infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustule			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyoderma			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rickettsiosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Salpingitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SARS-CoV-2 sepsis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scarlet fever			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic phlebitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis bacterial			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syphilis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic viral infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tinea capitis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis bacterial			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	4 / 13380 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	5 / 13380 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Typhoid fever			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5990 (0.00%)	1 / 2939 (0.03%)	3 / 13380 (0.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethritis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	3 / 5990 (0.05%)	2 / 2939 (0.07%)	9 / 13380 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 5990 (0.02%)	5 / 2939 (0.17%)	23 / 13380 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral myocarditis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pharyngitis			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	4 / 13380 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 5990 (0.02%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Abnormal weight gain			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	2 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	1 / 13380 (0.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic syndrome			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 5990 (0.00%)	0 / 2939 (0.00%)	0 / 13380 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo (Part 3)		
Total subjects affected by serious adverse events			
subjects affected / exposed	397 / 6487 (6.12%)		
number of deaths (all causes)	7		
number of deaths resulting from adverse events	6		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Alveolar rhabdomyosarcoma			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Benign ovarian tumour				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign hydatidiform mole				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Desmoplastic small round cell tumour				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cutaneous T-cell lymphoma				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carcinoma in situ				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ependymoma malignant				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibroadenoma of breast				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hodgkin's disease				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inflammatory myofibroblastic tumour				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Leukaemia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipoma				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian germ cell endodermal sinus tumour stage IV				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Osteochondroma				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medulloblastoma				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papillary thyroid cancer				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Schwannoma				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulcerated haemangioma				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Behcet's syndrome			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Embolism			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extremity necrosis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypertensive urgency			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kawasaki's disease			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyarteritis nodosa			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subgaleal haematoma			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vasculitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion complete			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion missed			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion incomplete			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abortion spontaneous			
subjects affected / exposed	7 / 6487 (0.11%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous incomplete			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion threatened			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cephalo-pelvic disproportion			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anembryonic gestation			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
False labour			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eclampsia			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
High risk pregnancy			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperemesis gravidarum			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Labour complication			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyhydramnios			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental insufficiency			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum haemorrhage			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	4 / 6487 (0.06%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Premature delivery			

subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Premature rupture of membranes				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Premature labour				
subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Premature separation of placenta				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Preterm premature rupture of membranes				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ruptured ectopic pregnancy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stillbirth				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Threatened labour				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Traumatic delivery				

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical cord prolapse				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Unstable foetal lie				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Chest pain				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hanging				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drowning				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Influenza like illness				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Organ failure				

subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Serositis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Allergy to arthropod bite				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic shock				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anaphylactic reaction				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Food allergy				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Drug hypersensitivity				

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemophagocytic lymphohistiocytosis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypersensitivity				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Type I hypersensitivity				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Social circumstances				
High risk sexual behaviour				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Substance use				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sexual abuse				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Physical assault				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Victim of crime				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Victim of sexual abuse				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Ovarian cyst				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Balanoposthitis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abnormal uterine bleeding				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovulation pain				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Testicular torsion				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Scrotal pain				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Penile adhesion				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulval haematoma				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asphyxia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenoidal hypertrophy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Asthmatic crisis				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bronchospasm				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoxia				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lupus pleurisy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Obstructive sleep apnoea syndrome				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus polyp				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wheezing				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tonsillar hypertrophy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Acute psychosis				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adjustment disorder				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adjustment disorder with depressed mood				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aggression				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Antisocial behaviour				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety disorder				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Behaviour disorder				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bipolar I disorder				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Completed suicide				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Depression				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Disruptive mood dysregulation disorder				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug abuse				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intentional self-injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Major depression				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mania				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mixed anxiety and depressive disorder			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oppositional defiant disorder			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric symptom			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Self-destructive behaviour			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychotic disorder			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Substance use disorder			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal behaviour			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	5 / 6487 (0.08%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device extrusion			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device malfunction			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholangitis sclerosing			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune hepatitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic steatosis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatosplenomegaly				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis acute				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic dysfunction-associated steatohepatitis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Portal hypertension				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Investigations				
False positive investigation result				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Red blood cell sedimentation rate increased				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural				

complications				
Abdominal injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Accidental exposure to product by child				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Accident at work				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alcohol poisoning				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Animal bite				
subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Arthropod bite				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthropod sting				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Avulsion fracture			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blindness traumatic			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burns second degree			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chemical burn of oral cavity			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Contusion			

subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Craniocerebral injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniofacial fracture			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electrical burn			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electric shock			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electric injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epidural haemorrhage			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extradural haematoma			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exposure to communicable disease			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epiphyseal injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eyelid injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Face injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foot fracture			

subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Forearm fracture				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Foreign body in gastrointestinal tract				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fractured coccyx				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gun shot wound				
subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Head injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hand fracture				
subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Ilium fracture				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				

subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatic rupture				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intentional overdose				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Joint injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint dislocation				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaw fracture				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament sprain				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Limb crushing injury				

subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Limb traumatic amputation			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lip injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver contusion			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple injuries			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle strain			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle injury			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neck injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Open globe injury			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Patella fracture			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic fracture			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penetrating abdominal trauma			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax traumatic			

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Perineal injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural discharge				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative adhesion				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Shunt malfunction				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin injury				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull fracture			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin laceration			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skull fractured base			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Soft tissue injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Snake bite			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord injury thoracic			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic rupture			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sports injury			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stab wound			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon injury			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Testicular injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thoracic vertebral fracture			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tooth fracture			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tibia fracture				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Traumatic haematoma				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Traumatic haemothorax				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial haemorrhage				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic liver injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic lung injury				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Ulna fracture				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper limb fracture				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Venom poisoning				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulvovaginal injury				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist fracture				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Atrial septal defect				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriovenous malformation				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral arteriovenous malformation haemorrhagic			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular arteriovenous malformation			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital cystic kidney disease			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cryptorchism			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermoid cyst			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Familial periodic paralysis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular dystrophy			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phimosis			

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Thalassaemia alpha				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute myocardial infarction				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aortic valve incompetence				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrhythmia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rheumatic heart disease				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinus node dysfunction				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular arrhythmia				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Acute disseminated encephalomyelitis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aqueductal stenosis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ataxia			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bell's palsy			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain hypoxia			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebellar infarction			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral venous thrombosis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diplegia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile convulsion				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Generalised tonic-clonic seizure				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Guillain-Barre syndrome				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hydrocephalus				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoaesthesia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ischaemic stroke				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Idiopathic generalised epilepsy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Optic neuritis				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Myelopathy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Partial seizures				

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post-traumatic headache				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Presyncope				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Quadriparesis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychogenic seizure				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ruptured cerebral aneurysm				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Serotonin syndrome				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Simple partial seizures				

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Status migrainosus				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Tension headache				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anaemia of pregnancy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood loss anaemia				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Deficiency anaemia				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disseminated intravascular coagulation			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Febrile neutropenia			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune thrombocytopenia			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mesenteric lymphadenitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Thrombotic thrombocytopenic purpura			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenic purpura				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
Cataract				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amaurosis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Conjunctivitis allergic				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Corneal opacity				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myopia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Refraction disorder				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orbital myositis				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retinal haemorrhage				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Abdominal pain lower				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acid peptic disease				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aphthous ulcer				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Colitis				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspepsia			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food poisoning			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Faecaloma			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	3 / 6487 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastritis erosive			

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhagic erosive gastritis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus paralytic				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Incarcerated umbilical hernia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intra-abdominal fluid collection				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Irritable bowel syndrome			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large intestine polyp			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoid hyperplasia of intestine			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mechanical ileus			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal varices haemorrhage			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Mesenteric cyst			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophagitis			

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatic pseudocyst				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal polyp				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal perforation				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				

subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erythema annulare			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psoriasis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lichen planus			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkeratosis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
End stage renal disease			

subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Calculus urinary			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive nephropathy			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis acute			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis chronic			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis proliferative			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glomerulonephritis rapidly progressive			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephritic syndrome			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lupus nephritis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
IgA nephropathy				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nephrotic syndrome				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post infection glomerulonephritis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post streptococcal glomerulonephritis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelocaliectasis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal colic				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urethral caruncle				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureterolithiasis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal failure				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary bladder rupture				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocrine disorders				
Hyperthyroidism				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Goitre				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cushing's syndrome				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypothyroidism				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis reactive			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epiphysiolysis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Costochondritis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exostosis of jaw			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extremity contracture			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibromyalgia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Greater trochanteric pain syndrome				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Juvenile idiopathic arthritis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Knee deformity				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle fatigue				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Neck pain				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rheumatic fever			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spondylitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic lupus erythematosus			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess jaw			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion infected			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess limb			

subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Abscess of external ear			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess neck			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess soft tissue			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute sinusitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acarodermatitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amniotic cavity infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amoebic dysentery			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Amoebiasis			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal abscess			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Appendiceal abscess			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	27 / 6487 (0.42%)		
occurrences causally related to treatment / all	0 / 27		
deaths causally related to treatment / all	0 / 0		
Appendicitis perforated			
subjects affected / exposed	6 / 6487 (0.09%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Arboviral infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascariasis			

subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacterial sepsis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial infection				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacterial vaginosis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacteriuria				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bartholin's abscess				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast abscess				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis				

subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cellulitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis viral			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bullous impetigo			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burkholderia pseudomallei infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Burn infection			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	24 / 6487 (0.37%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	7 / 6487 (0.11%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			

subjects affected / exposed	3 / 6487 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Chikungunya virus infection			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cellulitis orbital			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholera			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronavirus infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Conjunctivitis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Complicated appendicitis			
subjects affected / exposed	7 / 6487 (0.11%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Croup infectious			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis			

subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	83 / 6487 (1.28%)		
occurrences causally related to treatment / all	0 / 83		
deaths causally related to treatment / all	0 / 0		
Dengue haemorrhagic fever			
subjects affected / exposed	12 / 6487 (0.18%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Dermatitis infected			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea infectious			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disseminated tuberculosis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Enteritis infectious			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysentery			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epididymitis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema infectiosum				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia sepsis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye infection gonococcal				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Extradural abscess				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Focal peritonitis				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Folliculitis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gangrene				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis viral				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	11 / 6487 (0.17%)			
occurrences causally related to treatment / all	0 / 11			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis bacterial				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis salmonella				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis shigella				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal bacterial infection				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Groin abscess			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Giardiasis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis A			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis viral			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes simplex encephalitis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infected bite			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Impetigo			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infectious mononucleosis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infective exacerbation of asthma			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	9 / 6487 (0.14%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Infective myositis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint abscess			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Localised infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leptospirosis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	3 / 6487 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ludwig angina			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung abscess			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymph gland infection			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymph node tuberculosis			

subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenitis bacterial			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malaria			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Measles			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis tuberculous			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis aseptic			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle abscess			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstetric infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral herpes			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Orchitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis chronic			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis externa			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parasite allergy			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paranasal sinus abscess			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Parasitic gastroenteritis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Parotitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic abscess			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital abscess			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pelvic inflammatory disease			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Periorbital cellulitis			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	3 / 6487 (0.05%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pharyngitis bacterial			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngotonsillitis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	8 / 6487 (0.12%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Pilonidal disease			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia bacterial			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia influenzal			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia mycoplasmal			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia viral			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pseudomembranous colitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum sepsis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Puerperal infection			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary tuberculosis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pustule			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	4 / 6487 (0.06%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Pyoderma			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhinitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rickettsiosis			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Salpingitis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SARS-CoV-2 sepsis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scarlet fever				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	4 / 6487 (0.06%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Septic phlebitis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	2 / 6487 (0.03%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sinusitis bacterial				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal abscess			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal infection			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Superinfection			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syphilis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suspected COVID-19			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Systemic viral infection			

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	3 / 6487 (0.05%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Tinea capitis			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis bacterial			
subjects affected / exposed	2 / 6487 (0.03%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection bacterial			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	1 / 6487 (0.02%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Typhoid fever			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	4 / 6487 (0.06%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Urethritis			

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicella				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vaginal infection				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	15 / 6487 (0.23%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	17 / 6487 (0.26%)			
occurrences causally related to treatment / all	0 / 17			
deaths causally related to treatment / all	0 / 0			
Viral myocarditis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral pharyngitis				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral rash				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				

subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Abnormal weight gain				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	3 / 6487 (0.05%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	0 / 6487 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				
subjects affected / exposed	1 / 6487 (0.02%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolic syndrome				

subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obesity			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Placebo (Part 1)	Placebo (Part 2)	TDV (Part 2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	527 / 6687 (7.88%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	337 / 6687 (5.04%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences (all)	1145	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	363 / 6687 (5.43%)	0 / 6519 (0.00%)	0 / 13033 (0.00%)
occurrences (all)	779	0	0

Non-serious adverse events	TDV (Part 5)	TDV (Part 3)	Placebo (Part 4)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	149 / 2985 (4.99%)
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	82 / 2985 (2.75%)
occurrences (all)	0	0	250
General disorders and administration site conditions			

Pain			
subjects affected / exposed	0 / 5889 (0.00%)	0 / 12961 (0.00%)	113 / 2985 (3.79%)
occurrences (all)	0	0	243

Non-serious adverse events	TDV (Part 4)	Placebo (Part 5)	TDV (Part 1)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	409 / 5990 (6.83%)	0 / 2939 (0.00%)	1260 / 13380 (9.42%)
Nervous system disorders			
Headache			
subjects affected / exposed	206 / 5990 (3.44%)	0 / 2939 (0.00%)	736 / 13380 (5.50%)
occurrences (all)	561	0	2475
General disorders and administration site conditions			
Pain			
subjects affected / exposed	340 / 5990 (5.68%)	0 / 2939 (0.00%)	1011 / 13380 (7.56%)
occurrences (all)	758	0	2745

Non-serious adverse events	Placebo (Part 3)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 6487 (0.00%)		
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 6487 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 November 2015	Following changes were implemented with Protocol Amendment 2: -The protocol was primarily amended to change the dosing regimen and to modify the long-term febrile surveillance methodology (during Part 3). -Updated the role of Data Monitoring Committee and addition of involvement of Adjudication Committee. -Added second trial vaccination on Day 90 (Month 3). -Updated time window between trial visits and specification of trial procedures for each year of follow-up during Part 3. -Updated trial objectives and endpoints. -Removed conditional booster. -Replacement of enhanced passive hospital-based surveillance by modified active surveillance. -Six-month cap on pre-vaccination surveillance for dengue replaced by 10 months. -Addition of febrile illness surveillance during dry-run. -Updated the section on collection of serious adverse events. -Specifications added on use of interactive web/voice response system (IWRS/IVRS) for subject enrollment/randomisation. -Updates to certain study procedures, statistical analysis, and eligibility criteria.
18 May 2020	Following changes were implemented with Protocol Amendment 4: -Added a booster phase to the ongoing DEN-301 trial. -Subheadings were generated to differentiate between Parts 1, 2, and 3 of the trial and the new booster phase of the trial (Parts 4 and 5). -Microneutralization test (MNT) was replaced with MNT50 for consistency. -The term 'Legally Authorized Representative (LAR)' was replaced by parent/guardian for consistency. -The administrative trial information was updated and minor grammatical and editorial changes were included.
20 April 2021	Following changes were implemented with Protocol Amendment 4: - EudraCT Number was added. -Updated the status of the Interim Clinical Study Reports planned for the trial. -Corrected and updated list of References.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported