Clinical trial results:
A Phase 3, Randomized, Double-blinded, Placebo-controlled Trial to Evaluate the Efficacy and Safety of a Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Infants Born to Women Vaccinated During Pregnancy

Summary

EudraCT number	2019-002943-85
Trial protocol	DK FI NL
Global end of trial date	27 October 2023

Results information

Result version number	v1 (current)
This version publication date	10 May 2024
First version publication date	10 May 2024

Trial information

Trial identification

Sponsor protocol code	C3671008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04424316
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235E42nd Street, New York, United States, NY 10017
Public contact	PfizerClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	PfizerClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

For infant participants: the primary efficacy objective of this study was to evaluate the efficacy of respiratory syncytial virus stabilized prefusion F subunit vaccine (RSVpreF) in reducing the incidence of medically attended lower respiratory tract illness (MA-LRTI) and severe MA-LRTI due to RSV. The primary safety objective was to describe the safety of RSVpreF. For maternal participants: the primary objective was to describe the safety and tolerability of RSVpreF.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 June 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	2 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 1860
Country: Number of subjects enrolled	Australia: 48
Country: Number of subjects enrolled	Brazil: 145
Country: Number of subjects enrolled	Canada: 110
Country: Number of subjects enrolled	Chile: 342
Country: Number of subjects enrolled	Denmark: 123
Country: Number of subjects enrolled	Finland: 296
Country: Number of subjects enrolled	Gambia: 389
Country: Number of subjects enrolled	Japan: 926
Country: Number of subjects enrolled	Korea, Republic of: 24
Country: Number of subjects enrolled	Mexico: 149
Country: Number of subjects enrolled	Netherlands: 384
Country: Number of subjects enrolled	New Zealand: 197
Country: Number of subjects enrolled	Philippines: 156
Country: Number of subjects enrolled	South Africa: 1900
Country: Number of subjects enrolled	Spain: 484

Country: Number of subjects enrolled	Taiwan: 520
Country: Number of subjects enrolled	United States: 6637
Worldwide total number of subjects	14690
EEA total number of subjects	1287

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	379
Newborns (0-27 days)	6926
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	18
Adults (18-64 years)	7367
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 14690 participants were enrolled at multiple sites (maternal - 7385 and infant - 7305 participants).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Maternal Participants: RSVpreF

Arm description:

Study-eligible pregnant women (maternal participants) were randomized to receive a single dose of 120 micrograms (mcg) RSVpreF, intramuscularly (IM) on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.

Arm type	Experimental
Investigational medicinal product name	RSVpreF
Investigational medicinal product code	PF-06928316
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Study-eligible pregnant women (maternal participants) upon randomization received a single dose of 120 mcg RSVpreF, intramuscularly in the deltoid muscle of the non-dominant arm on Day 1 (day of vaccination).

Arm title	Maternal Participants: Placebo

Arm description:

Maternal participants were randomized to receive placebo matching to RSVpreF as a single dose on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.

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

Dosage and administration details:

Study-eligible pregnant women (maternal participants) upon randomization received a single dose of placebo (matched to RSVpreF but no active vaccine), intramuscularly in the deltoid muscle of the non-dominant arm on Day 1 (day of vaccination).

Arm title	Infant Participants: RSVpreF

Arm description:

Infant participants born to maternal participants vaccinated with a single dose of 120 mcg RSVpreF were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.

Arm type	No intervention

No investigational medicinal product assigned in this arm	
Arm title	Infant Participants: Placebo

Arm description:

Infant participants born to maternal participants who received placebo (matching RSVpreF without active vaccine) were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.

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

Number of subjects in period 1	Maternal Participants: RSVpreF	Maternal Participants: Placebo	Infant Participants: RSVpreF
Started	3698	3687	3659
Completed	3516	3509	3318
Not completed	182	178	341
Physician decision	1	-	1
Consent withdrawn by subject	71	77	-
Adverse event, non-fatal	-	1	-
Death	1	-	8
No longer met eligibility criteria	1	-	-
Unspecified	15	11	34
Lost to follow-up	93	88	224
Withdrawal by parent/guardian	-	-	74
Protocol deviation	-	1	-

Number of subjects in period 1	Infant Participants: Placebo
Started	3646
Completed	3294
Not completed	352
Physician decision	1
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Death	14
No longer met eligibility criteria	-
Unspecified	45
Lost to follow-up	211
Withdrawal by parent/guardian	81
Protocol deviation	-

Baseline characteristics

Reporting groups	
Reporting group title	Maternal Participants: RSVpreF
Reporting group description:	
Study-eligible pregnant women (maternal participants) were randomized to receive a single dose of 120 micrograms (mcg) RSVpreF, intramuscularly (IM) on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.	
Reporting group title	Maternal Participants: Placebo
Reporting group description:	
Maternal participants were randomized to receive placebo matching to RSVpreF as a single dose on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.	
Reporting group title	Infant Participants: RSVpreF
Reporting group description:	
Infant participants born to maternal participants vaccinated with a single dose of 120 mcg RSVpreF were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.	
Reporting group title	Infant Participants: Placebo
Reporting group description:	
Infant participants born to maternal participants who received placebo (matching RSVpreF without active vaccine) were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.	

Reporting group values	Maternal Participants: RSVpreF	Maternal Participants: Placebo	Infant Participants: RSVpreF
Number of subjects	3698	3687	3659
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	207
Newborns (0-27 days)	0	0	3452
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	9	9	0
Adults (18-64 years)	3689	3678	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Infants are born to the maternal participants that received RSVpreF or placebo. Timeline at birth is 0. This represents the mean age of maternal and infant participants respectively, at the time of enrolment.			
Units: years			
arithmetic mean	29.0	29.0	0
standard deviation	± 5.64	± 5.75	± 0
Gender Categorical Units: Participants			
Female	3698	3687	1794
Male	0	0	1865

Race Units: Subjects			
American Indian or Alaska Native	38	37	42
Asian	456	464	446
Native Hawaiian or Other Pacific Islander	9	12	13
Black or African American	720	725	706
White	2397	2375	2340
More than one race	30	21	65
Unknown or Not Reported	48	53	47
Ethnicity Units: Subjects			
Hispanic or Latino	1063	1086	1079
Not Hispanic or Latino	2605	2568	2529
Unknown or Not Reported	30	33	51

Reporting group values	Infant Participants: Placebo	Total	
Number of subjects	3646	14690	
Age Categorical Units: Participants			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	172	379	
Newborns (0-27 days)	3474	6926	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	18	
Adults (18-64 years)	0	7367	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous			
Infants are born to the maternal participants that received RSVpreF or placebo. Timeline at birth is 0. This represents the mean age of maternal and infant participants respectively, at the time of enrolment.			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender Categorical Units: Participants			
Female	1815	10994	
Male	1831	3696	
Race Units: Subjects			
American Indian or Alaska Native	36	153	
Asian	456	1822	
Native Hawaiian or Other Pacific Islander	11	45	
Black or African American	706	2857	
White	2328	9440	
More than one race	59	175	
Unknown or Not Reported	50	198	
Ethnicity Units: Subjects			

Hispanic or Latino	1081	4309	
Not Hispanic or Latino	2519	10221	
Unknown or Not Reported	46	160	

End points

End points reporting groups

Reporting group title	Maternal Participants: RSVpreF

Reporting group description:

Study-eligible pregnant women (maternal participants) were randomized to receive a single dose of 120 micrograms (mcg) RSVpreF, intramuscularly (IM) on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.

Reporting group title	Maternal Participants: Placebo

Reporting group description:

Maternal participants were randomized to receive placebo matching to RSVpreF as a single dose on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.

Reporting group title	Infant Participants: RSVpreF

Reporting group description:

Infant participants born to maternal participants vaccinated with a single dose of 120 mcg RSVpreF were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.

Reporting group title	Infant Participants: Placebo

Reporting group description:

Infant participants born to maternal participants who received placebo (matching RSVpreF without active vaccine) were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.

Primary: Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 90 Days After Birth (Efficacy)

End point title	Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 90 Days After Birth (Efficacy)[1]

End point description:

Results are presented as confirmed by endpoint adjudication committee. MA-LRTI case: Infant with an MA-RTI visit with age related fast breathing (respiratory rate [RR] more than or equal to [=>]60 beats per minute [bpm] for less than [<]2 months of age [<60 days of age], =>50 bpm for =>2 months to <12 months of age, or =>40 bpm for =>12 months to 24 months of age) or oxygen saturation (SpO2) <95% or chest wall indrawing. The causative pathogen was to be determined but may meet endpoint definition if RSV-positivity was confirmed per study requirements. Evaluable efficacy - infant population= all infant participants who were born to maternal participants who did not have major protocol deviations prior to the delivery and who received the investigational product to which they were randomized at least 14 days prior to delivery, were eligible, had no major protocol deviations. "Number of Participants Analyzed"= number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 90 Days after birth

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	0.7	1.7		

Statistical analyses

Statistical analysis title	RSVpreF versus placebo

Statistical analysis description:

Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine Efficacy
Point estimate	57.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.3
upper limit	74.6

Primary: Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 150 Days After Birth (Efficacy)

End point title	Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 150 Days After Birth (Efficacy)[2]

End point description:

Results are presented as confirmed by endpoint adjudication committee. MA-LRTI case: Infant with an MA-RTI visit with age related fast breathing (RR =>60 bpm for <2 months of age [<60 days of age], =>50 bpm for =>2 months to <12 months of age, or =>40 bpm for =>12 months to 24 months of age) or SpO2 <95% or chest wall indrawing. The causative pathogen was to be determined but may meet endpoint definition if RSV-positivity was confirmed per study requirements. Evaluable efficacy - infant population= all infant participants who were born to maternal participants who did not have major protocol deviations prior to the delivery and who received the investigational product to which they were randomized at least 14 days prior to delivery, were eligible, had no major protocol deviations. "Number of Participants Analyzed"= number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 150 Days after birth

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	1.5	3.1		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine Efficacy
Point estimate	50
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.3
upper limit	64.5

Primary: Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 120 Days After Birth (Efficacy)

End point title	Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 120 Days After Birth (Efficacy)[3]

End point description:

Results are presented as confirmed by endpoint adjudication committee. MA-LRTI case: Infant with an MA-RTI visit with age related fast breathing (RR =>60 bpm for <2 months of age [<60 days of age], =>50 bpm for =>2 months to <12 months of age, or =>40 bpm for =>12 months to 24 months of age) or SpO2 <95% or chest wall indrawing. The causative pathogen was to be determined but may meet endpoint definition if RSV-positivity was confirmed per study requirements. Evaluable efficacy - infant population= all infant participants who were born to maternal participants who did not have major protocol deviations prior to the delivery and who received the investigational product to which they were randomized at least 14 days prior to delivery, were eligible, had no major protocol deviations. "Number of Participants Analyzed"= number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 120 Days after birth

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	1.1	2.5		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine Efficacy
Point estimate	54.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.2
upper limit	69.5

Primary: Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 120 Days After Birth (Efficacy)

End point title	Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 120 Days After Birth (Efficacy)[4]

End point description:

Results are presented as confirmed by endpoint adjudication committee. Severe MA-LRTI cases were a subset of MA-LRTI cases, and all severe MA-LRTI cases were considered MA-LRTI cases. Severe MA-LRTI case was a RSV positively adjudicated event which met the following defined criteria: An infant with an MA-RTI visit and aged associated fast breathing (RR =>70 bpm for <2 months of age [<60 days of age], =>60 bpm for =>2 months to <12 months of age, or =>50 bpm for =>12 months to 24 months of age) or SpO2 <93% or high-flow nasal cannula or mechanical ventilation (i.e., invasive or noninvasive) or ICU admission for more than (>)4 hours or failure to respond/unconscious. Evaluable efficacy - infant population was used. Here, "Number of Participants Analyzed" signifies number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 120 Days after birth

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	0.4	1.4		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine Efficacy
Point estimate	73.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.3
upper limit	86.8

Primary: Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 90 Days After Birth (Efficacy)

End point title	Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 90 Days After Birth (Efficacy)[5]

End point description:

Results are presented as confirmed by endpoint adjudication committee. Severe MA-LRTI cases were a subset of MA-LRTI cases, and all severe MA-LRTI cases were considered MA-LRTI cases. Severe MA-LRTI case was a RSV positively adjudicated event which met the following defined criteria: An infant with an MA-RTI visit and aged associated fast breathing (RR =>70 bpm for <2 months of age [<60 days of age], =>60 bpm for =>2 months to <12 months of age, or =>50 bpm for =>12 months to 24 months of age) or SpO2 <93% or high-flow nasal cannula or mechanical ventilation (i.e., invasive or noninvasive) or ICU admission for more than (>)4 hours or failure to respond/unconscious. Evaluable efficacy - infant population was used. Here, "Number of Participants Analyzed" signifies number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 90 Days after birth

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	0.2	1.0		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo
Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority[6]
Parameter estimate	Vaccine Efficacy
Point estimate	82.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	57.5
upper limit	93.9

Notes:

[6] - Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Primary: Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 180 Days After Birth (Efficacy)

End point title	Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 180 Days After Birth (Efficacy)[7]

End point description:

Results are presented as confirmed by endpoint adjudication committee. MA-LRTI case: Infant with an MA-RTI visit with age related fast breathing (RR =>60 bpm for <2 months of age [<60 days of age], =>50 bpm for =>2 months to <12 months of age, or =>40 bpm for =>12 months to 24 months of age) or SpO2 <95% or chest wall indrawing. The causative pathogen was to be determined but may meet endpoint definition if RSV-positivity was confirmed per study requirements. Evaluable efficacy - infant population= all infant participants who were born to maternal participants who did not have major protocol deviations prior to the delivery and who received the investigational product to which they were randomized at least 14 days prior to delivery, were eligible, had no major protocol deviations. "Number of Participants Analyzed"= number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 180 Days after birth

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	1.9	3.7		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine Efficacy
Point estimate	49.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	31.4
upper limit	62.8

Primary: Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 150 Days After Birth (Efficacy)

End point title	Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 150 Days After Birth (Efficacy)[8]

End point description:

Results are presented as confirmed by endpoint adjudication committee. Severe MA-LRTI cases were a subset of MA-LRTI cases, and all severe MA-LRTI cases were considered MA-LRTI cases. Severe MA-LRTI case was a RSV positively adjudicated event which met the following defined criteria: An infant with an MA-RTI visit and aged associated fast breathing (RR =>70 bpm for <2 months of age [<60 days of age], =>60 bpm for =>2 months to <12 months of age, or =>50 bpm for =>12 months to 24 months of age) or SpO2 <93% or high-flow nasal cannula or mechanical ventilation (i.e., invasive or noninvasive) or ICU admission for more than (>)4 hours or failure to respond/unconscious. Evaluable efficacy - infant population was used. Here, "Number of Participants Analyzed" signifies number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 150 Days after birth

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	0.5	1.7		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine Efficacy
Point estimate	70.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	49.4
upper limit	83.6

Primary: Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 180 Days After Birth (Efficacy)

End point title	Percentage of Severe MA-LRTI Cases due to RSV in Infant Participants Occurring Within 180 Days After Birth (Efficacy)[9]

End point description:

Results are presented as confirmed by endpoint adjudication committee. Severe MA-LRTI cases were a subset of MA-LRTI cases, and all severe MA-LRTI cases were considered MA-LRTI cases. Severe MA-LRTI case was a RSV positively adjudicated event which met the following defined criteria: An infant with an MA-RTI visit and aged associated fast breathing (RR =>70 bpm for <2 months of age [<60 days of age], =>60 bpm for =>2 months to <12 months of age, or =>50 bpm for =>12 months to 24 months of age) or SpO2 <93% or high-flow nasal cannula or mechanical ventilation (i.e., invasive or noninvasive) or ICU admission for more than (>)4 hours or failure to respond/unconscious. Evaluable efficacy - infant population was used. Here, "Number of Participants Analyzed" signifies number of participants included in evaluable efficacy - infant population.

End point type	Primary

End point timeframe:

Within 180 Days after birth

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of cases				
number (not applicable)	0.6	2.0		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine Efficacy
Point estimate	70
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.6
upper limit	82.5

Primary: Percentage of Infant Participants With Adverse Events of Special Interest (AESI) (Safety)

End point title	Percentage of Infant Participants With Adverse Events of Special Interest (AESI) (Safety)[10][11]

End point description:

AESI: Subset of targeted medical events based on review of known pharmacology, toxicology findings, possible class effects, published literature, and signals arising from safety data assessments, and on population under study. AESI's were based on targeted medical events associated with pregnant maternal participants and their infants prior to/during delivery and at birth. For infant participants AESI: Preterm birth (born at <37weeks gestation); birth weight 1001-2500 grams; developmental delay; positive viral (polymerase chain reaction [PCR] or antigen-based) testing for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), when not reported during MA-RTI visit, were reported as SARS-CoV-2 test positive. Extremely preterm birth (<28weeks), extremely low birth weight (=<1000 g) were reported AESI as SAE. Infant safety population: infant participants born to vaccinated maternal participants. "Number of Participants Analyzed"= participants included in infant safety population.

End point type	Primary

End point timeframe:

Birth to 24 Months of age

Notes:

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

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3659	3646		
Units: Percentage of participants				
number (confidence interval 95%)	11.9 (10.8 to 13.0)	10.3 (9.3 to 11.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants According to Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) Score at 1 Minute After Birth (Safety)

End point title	Percentage of Infant Participants According to Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) Score at 1 Minute After Birth (Safety)[12][13]

End point description:

APGAR was a fast evaluation technique used to evaluate a newborn baby's overall health immediately after birth, and at 5 or 10 minutes later. APGAR stands for (A) Appearance (skin coloration), (P) Pulse (heart rate), (G) Grimace (reflex response), (A) Activity (muscle tone) and (R) Respiration (breathing). Each component was given a score of 0, 1, or 2 for a total possible score of 0-10, where higher scores indicate better health. A score of 7 to 10 was good, 4 to <7 was moderate, and <4 is poor. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies number of participants included in infant safety population.

End point type	Primary

End point timeframe:

1 Minute after birth

Notes:

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

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3625	3606		
Units: Percentage of participants				
number (not applicable)				
Score Less than (<)4	1.4	1.2		
Score 4 to <7	3.7	3.4		
Score 7 to 10	94.9	95.3		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants With Other Neonatal Events (Safety)

End point title	Percentage of Infant Participants With Other Neonatal Events (Safety)[14][15]

End point description:

Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies number of participants included in infant safety population.

End point type	Primary

End point timeframe:

Within 1 Month after birth

Notes:

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

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3659	3646		
Units: Percentage of participants				
number (not applicable)	6.2	5.5		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants With Congenital Malformations/Anomalies (Safety)

End point title	Percentage of Infant Participants With Congenital Malformations/Anomalies (Safety)[16][17]

End point description:

Congenital malformations/ anomalies were defined as structural or functional anomalies that occurred during intrauterine life and could be identified prenatally, at birth or later in life. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies number of participants included in infant safety population.

End point type	Primary

End point timeframe:

At birth

Notes:

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

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3659	3646		
Units: Percentage of participants				
number (not applicable)	5.6	6.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants With Neonatal Deaths (Safety)

End point title	Percentage of Infant Participants With Neonatal Deaths (Safety)[18][19]

End point description:

Neonatal death was defined as the death of a live-born infant that occurred within a month after birth. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies number of participants included in infant safety population.

End point type	Primary

End point timeframe:

Within 1 Month after birth

Notes:

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

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3659	3646		
Units: Percentage of participants				
number (confidence interval 95%)	0.1 (0.0 to 0.2)	0.1 (0.0 to 0.3)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants According to APGAR Score at 5 Minutes After Birth (Safety)

End point title	Percentage of Infant Participants According to APGAR Score at 5 Minutes After Birth (Safety)[20][21]

End point description:

APGAR was a fast evaluation technique used to evaluate a newborn baby's overall health immediately after birth, and at 5 or 10 minutes later. APGAR stands for (A) Appearance (skin coloration), (P) Pulse

(heart rate), (G) Grimace (reflex response), (A) Activity (muscle tone) and (R) Respiration (breathing). Each component was given a score of 0, 1, or 2 for a total possible score of 0-10, where higher scores indicate better health. A score of 7 to 10 was good, 4 to <7 was moderate, and <4 is poor. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies number of participants included in infant safety population.

End point type	Primary

End point timeframe:

5 Minutes after birth

Notes:

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

[21] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3618	3602		
Units: Percentage of participants				
number (not applicable)				
Score <4	0.2	0.1		
Score 4 to <7	0.8	0.7		
Score 7 to 10	99.0	99.1		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants According to APGAR Score at 10 Minutes After Birth (Safety)

End point title	Percentage of Infant Participants According to APGAR Score at 10 Minutes After Birth (Safety)[22][23]

End point description:

APGAR was a fast evaluation technique used to evaluate a newborn baby's overall health immediately after birth, and at 5 or 10 minutes later. APGAR stands for (A) Appearance (skin coloration), (P) Pulse (heart rate), (G) Grimace (reflex response), (A) Activity (muscle tone) and (R) Respiration (breathing). Each component was given a score of 0, 1, or 2 for a total possible score of 0-10, where higher scores indicate better health. A score of 7 to 10 was good, 4 to <7 was moderate, and <4 is poor. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies number of participants included in infant safety population.

End point type	Primary

End point timeframe:

10 Minutes after birth

Notes:

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

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	999	999		
Units: Percentage of participants				
number (not applicable)				
Score <4	0	0		
Score 4 to <7	0.6	0.4		
Score 7 to 10	99.4	99.6		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants With Adverse Events (AEs) From Birth to 1 Month of Age (Safety)

End point title	Percentage of Infant Participants With Adverse Events (AEs) From Birth to 1 Month of Age (Safety)[24][25]

End point description:

An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies number of participants included in infant safety population.

End point type	Primary

End point timeframe:

From birth to 1 Month of age

Notes:

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

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3659	3646		
Units: Percentage of participants				
number (confidence interval 95%)	38.0 (36.4 to 39.6)	35.4 (33.9 to 37.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants With Serious Adverse Events (SAEs) and

Newly Diagnosed Chronic Medical Conditions (NDCMCs) From Birth Through 6 Months of Age (Safety)

End point title	Percentage of Infant Participants With Serious Adverse Events (SAEs) and Newly Diagnosed Chronic Medical Conditions (NDCMCs) From Birth Through 6 Months of Age (Safety)[26][27]

End point description:

An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, resulted in congenital anomaly/birth defect or that was considered an important medical event. A NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies participants included in infant safety population and evaluable for this endpoint.

End point type	Primary

End point timeframe:

From birth to 6 Months of age

Notes:

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

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3568	3558		
Units: Percentage of participants				
number (confidence interval 95%)				
SAE	16.7 (15.5 to 17.9)	16.4 (15.2 to 17.7)		
NDCMC	1.3 (0.9 to 1.7)	1.6 (1.2 to 2.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants With SAEs and NDCMCs From Birth Through 12 Months of Age (Safety)

End point title	Percentage of Infant Participants With SAEs and NDCMCs From Birth Through 12 Months of Age (Safety)[28][29]

End point description:

An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, resulted in congenital anomaly/birth defect or that was considered an important medical event. A NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies participants included in infant safety population and

evaluable for this endpoint.

End point type	Primary

End point timeframe:

From birth to 12 Months of age

Notes:

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

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3568	3558		
Units: Percentage of participants				
number (confidence interval 95%)				
SAE	17.3 (16.1 to 18.6)	17.2 (15.9 to 18.5)		
NDCMC	2.1 (1.7 to 2.6)	2.3 (1.9 to 2.9)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Infant Participants With SAEs and NDCMCs From Birth Through 24 Months of Age (Safety)

End point title	Percentage of Infant Participants With SAEs and NDCMCs From Birth Through 24 Months of Age (Safety)[30][31]

End point description:

An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, resulted in congenital anomaly/birth defect or that was considered an important medical event. A NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Infant safety population included all infant participants who were born to vaccinated maternal participants. Here, "Number of Participants Analyzed" signifies participants included in infant safety population and evaluable for this endpoint.

End point type	Primary

End point timeframe:

From birth to 24 Months of age

Notes:

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

[31] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3659	3646		
Units: Percentage of participants				
number (confidence interval 95%)				
SAE	19.0 (17.8 to 20.4)	18.9 (17.6 to 20.2)		
NDCMC	3.9 (3.3 to 4.6)	4.5 (3.8 to 5.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Participants With Prespecified Local Reactions (LR) Within 7 Days After Vaccination (Safety)

End point title	Percentage of Maternal Participants With Prespecified Local Reactions (LR) Within 7 Days After Vaccination (Safety)[32][33]

End point description:

Local reactions included redness, swelling, and pain at injection site and were recorded in electronic diary (e-diary). Redness and swelling were measured and recorded in measuring device units. 1 measuring device unit= 0.5 centimetre (cm). Redness and swelling were graded as mild (greater than [>]2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm), severe (>10.0 cm) and grade 4 (necrosis or exfoliative dermatitis). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), severe (prevented daily activity) and grade 4 (emergency room visit or hospitalization for the severe pain at the injection site). Maternal safety population included all randomised maternal participants who received investigational product. Here, "Number of Participants Analyzed" = number of participants included in maternal safety population and evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 Day follow-up period after vaccination

Notes:

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

[33] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for maternal participants.

End point values	Maternal Participants: RSVpreF	Maternal Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3678	3651		
Units: Percentage of participants				
number (confidence interval 95%)				
Redness: Any	7.2 (6.4 to 8.1)	0.2 (0.1 to 0.4)		
Redness: Mild	5.0 (4.3 to 5.7)	0.1 (0.0 to 0.3)		
Redness: Moderate	2.1 (1.7 to 2.6)	0.1 (0.0 to 0.3)		
Redness: Severe	0.1 (0.0 to 0.3)	0 (0.0 to 0.1)		
Redness: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Swelling: Any	6.2 (5.4 to 7.0)	0.2 (0.1 to 0.4)		

Swelling: Mild	4.1 (3.5 to 4.8)	0.1 (0.0 to 0.3)		
Swelling: Moderate	2.0 (1.6 to 2.5)	0.1 (0.0 to 0.2)		
Swelling: Severe	0.1 (0.0 to 0.2)	0 (0.0 to 0.1)		
Swelling: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Pain at injection site: Any	40.7 (39.1 to 42.3)	10.2 (9.2 to 11.2)		
Pain at injection site: Mild	36.1 (34.6 to 37.7)	9.3 (8.4 to 10.3)		
Pain at injection site: Moderate	4.5 (3.8 to 5.2)	0.9 (0.6 to 1.2)		
Pain at injection site: Severe	0.1 (0.0 to 0.3)	0 (0.0 to 0.1)		
Pain at injection site: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Participants With Prespecified Systemic Events (SE) Within 7 Days after Vaccination (Safety)

End point title	Percentage of Maternal Participants With Prespecified Systemic Events (SE) Within 7 Days after Vaccination (Safety)[34][35]

End point description:

Systemic events included: fever, fatigue, headache, nausea, muscle pain, joint pain, vomiting, and diarrhoea. Fever was classified as: =>38.0 degree Celsius [C]), 38.0-38.4, 38.5-38.9, 39.0 40.0 and >40.0 degree C. Headache, nausea, fatigue, muscle pain and joint pain were graded as mild (didn't interfere with activity), moderate (some interference with activity), severe (prevented daily activity) and grade 4 (emergency room visit or hospitalization). Vomiting: mild (1-2 times in 24 hours [H]), moderate (>2 times in 24 H), severe (required intravenous [IV] hydration) and grade 4 (emergency room visit or hospitalization). Diarrhoea: mild (2-3 loose stools in 24 H), moderate (4-5 loose stools in 24 H), severe (>=6 in 24 H) and grade 4 (emergency room visit or hospitalization). Maternal safety population evaluated. Here, "Number of Participants Analyzed"= participants included in maternal safety population and evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 Day follow-up period after vaccination

Notes:

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

[35] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for maternal participants.

End point values	Maternal Participants: RSVpreF	Maternal Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3678	3651		
Units: Percentage of participants				
number (confidence interval 95%)				
Fever: >=38.0 degree C	2.6 (2.1 to 3.1)	2.9 (2.4 to 3.5)		
Fever: 38.0 to 38.4 degree C	1.7 (1.3 to 2.1)	1.5 (1.1 to 2.0)		
Fever: 38.5 to 38.9 degree C	0.8 (0.5 to 1.1)	1.2 (0.8 to 1.6)		
Fever: 39.0 to 40.0 degree C	0.1 (0.0 to 0.2)	0.1 (0.0 to 0.3)		

Fever: >40.0 degree C	0.1 (0.0 to 0.2)	0.1 (0.0 to 0.3)		
Fatigue: Any	46.1 (44.5 to 47.7)	43.8 (42.2 to 45.4)		
Fatigue: Mild	23.5 (22.1 to 24.9)	22.7 (21.4 to 24.1)		
Fatigue: Moderate	21.3 (20.0 to 22.7)	19.6 (18.4 to 21.0)		
Fatigue: Severe	1.3 (1.0 to 1.8)	1.4 (1.1 to 1.9)		
Fatigue: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Headache: Any	31.0 (29.5 to 32.5)	27.6 (26.2 to 29.1)		
Headache: Mild	20.2 (18.9 to 21.5)	17.9 (16.7 to 19.2)		
Headache: Moderate	10.4 (9.4 to 11.4)	9.4 (8.5 to 10.4)		
Headache: Severe	0.4 (0.2 to 0.7)	0.4 (0.2 to 0.6)		
Headache: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Nausea: Any	20.0 (18.7 to 21.3)	19.3 (18.0 to 20.6)		
Nausea: Mild	14.4 (13.3 to 15.6)	13.9 (12.8 to 15.0)		
Nausea: Moderate	5.4 (4.7 to 6.1)	5.2 (4.5 to 6.0)		
Nausea: Severe	0.2 (0.1 to 0.4)	0.2 (0.1 to 0.4)		
Nausea: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Muscle pain: Any	26.6 (25.1 to 28.0)	17.1 (15.9 to 18.4)		
Muscle pain: Mild	17.6 (16.4 to 18.9)	10.0 (9.0 to 11.0)		
Muscle pain: Moderate	8.6 (7.7 to 9.5)	6.8 (6.0 to 7.7)		
Muscle pain: Severe	0.4 (0.2 to 0.6)	0.3 (0.2 to 0.6)		
Muscle pain: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Joint pain: Any	11.6 (10.6 to 12.7)	10.5 (9.5 to 11.6)		
Joint pain: Mild	6.5 (5.7 to 7.3)	6.0 (5.2 to 6.8)		
Joint pain: Moderate	4.9 (4.2 to 5.7)	4.4 (3.8 to 5.2)		
Joint pain: Severe	0.2 (0.1 to 0.4)	0.1 (0.0 to 0.2)		
Joint pain: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Vomiting: Any	7.9 (7.0 to 8.8)	7.0 (6.2 to 7.8)		
Vomiting: Mild	6.4 (5.6 to 7.2)	5.4 (4.7 to 6.1)		
Vomiting: Moderate	1.3 (0.9 to 1.7)	1.5 (1.2 to 2.0)		
Vomiting: Severe	0.2 (0.1 to 0.4)	0.1 (0.0 to 0.2)		
Vomiting: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		
Diarrhoea: Any	11.3 (10.3 to 12.3)	11.4 (10.4 to 12.5)		
Diarrhoea: Mild	9.1 (8.2 to 10.1)	9.4 (8.4 to 10.4)		
Diarrhoea: Moderate	2.0 (1.6 to 2.5)	1.9 (1.4 to 2.4)		
Diarrhoea: Severe	0.1 (0.0 to 0.3)	0.2 (0.1 to 0.4)		
Diarrhoea: Grade 4	0 (0.0 to 0.1)	0 (0.0 to 0.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Participants With AEs From the Time of Vaccination Through 1 Month After Vaccination (Safety)

End point title	Percentage of Maternal Participants With AEs From the Time of Vaccination Through 1 Month After Vaccination (Safety)[36][37]

End point description:

An AE was any untoward medical occurrence in a participant or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Maternal safety population included all randomised maternal participants who received investigational product. Here, "Number of Participants Analyzed" signifies participants included in maternal safety population.

End point type	Primary

End point timeframe:

1 Month after vaccination

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analysed only for maternal participants.

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for maternal participants.

End point values	Maternal Participants: RSVpreF	Maternal Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3698	3687		
Units: Percentage of participants				
number (confidence interval 95%)	14.0 (12.9 to 15.1)	13.2 (12.2 to 14.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Participants With SAEs Throughout the Study Period (Safety)

End point title	Percentage of Maternal Participants With SAEs Throughout the Study Period (Safety)[38][39]

End point description:

SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, resulted in congenital anomaly/birth defect or that was considered an important medical event. Maternal safety population included all randomised maternal participants who received investigational product. Here, "Number of Participants Analyzed" signifies participants included in maternal safety population.

End point type	Primary

End point timeframe:

Up to 6 Months

Notes:

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

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for maternal participants.

End point values	Maternal Participants: RSVpreF	Maternal Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3698	3687		
Units: Percentage of participants				
number (confidence interval 95%)	16.6 (15.4 to 17.8)	15.8 (14.6 to 17.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Hospitalizations due to RSV in Infant Participants Occurring Within 90, 120, 150, 180 and 360 Days After Birth (Efficacy)

End point title	Percentage of Hospitalizations due to RSV in Infant Participants Occurring Within 90, 120, 150, 180 and 360 Days After Birth (Efficacy)[40]

End point description:

Results are reported as confirmed by endpoint adjudication committee. The evaluable efficacy – infant population included all infant participants who are born to maternal participants who did not have major protocol deviations prior to the delivery and who received the investigational product to which they were randomized at least 14 days prior to delivery, were eligible, and had no major protocol deviations. Here, "Number of Participants Analyzed" signifies participants included in evaluable efficacy – infant population and evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Within 90, 120, 150, 180 and 360 Days after birth

Notes:

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3585	3563		
Units: Percentage of participants				
number (not applicable)				
90 days after birth	0.3	0.9		
120 days after birth	0.4	1.1		
150 days after birth	0.5	1.2		
180 days after birth	0.6	1.3		
360 days after birth	1.4	1.9		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 90 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	69.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	37.1
upper limit	86.7

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 120 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	61.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	28.6
upper limit	80.3

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 150 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo

Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	57.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.9
upper limit	76.8

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 180 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	55.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.8
upper limit	74.6

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 360 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	7148
Analysis specification	Post-hoc
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	24.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	48.6

Secondary: Percentage of MA-LRTI Cases due to any Cause With Protocol Defined Criteria in Infant Participants Occurring Within 90, 120, 150, 180 and 360 Days After Birth (Efficacy)

End point title	Percentage of MA-LRTI Cases due to any Cause With Protocol Defined Criteria in Infant Participants Occurring Within 90, 120, 150, 180 and 360 Days After Birth (Efficacy)[41]

End point description:

MA-LRTI cases due to any cause occurring within 90 days, 120 days, 150 days, 180 days, and 360 days after birth was defined as an infant with an MA-RTI visit with age related fast breathing (RR =>60 bpm for <2 months of age [<60 days of age], =>50 bpm for =>2 months to <12 months of age, or =>40 bpm for =>12 months to 24 months of age) or SpO2 <95% or chest wall indrawing. The evaluable efficacy - infant population included all infant participants who were born to maternal participants who did not have major protocol deviations prior to the delivery and who received the investigational product to which they were randomized at least 14 days prior to delivery, were eligible, and had no major protocol deviations. Here, "Number of Participants Analyzed" signifies number of participants included in evaluable efficacy - infant population and evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Within 90, 120, 150, 180 and 360 Days after birth

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3495	3480		
Units: Percentage of cases				
number (not applicable)				
90 days after birth	5.3	5.7		
120 days after birth	7.5	8.0		
150 days after birth	9.5	10.0		
180 days after birth	11.2	11.6		
360 days after birth	14.4	15.3		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 90 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	7

Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	-22.3
upper limit	29.3

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 120 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	6.1
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	-18.3
upper limit	25.5

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 360 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	5.1
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	-12.1
upper limit	19.6

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 180 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval

was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	2.5
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	-17.9
upper limit	19.4

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy within 150 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	5.2
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	-16.5
upper limit	22.8

Secondary: Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 210, 240, 270 and 360 Days After Birth (Efficacy)

End point title	Percentage of MA-LRTI Cases due to RSV in Infant Participants Occurring Within 210, 240, 270 and 360 Days After Birth (Efficacy)[42]

End point description:

Results are presented as confirmed by endpoint adjudication committee. MA-LRTI case: Infant with an MA-RTI visit with age related fast breathing (RR =>60 bpm for <2 months of age [<60 days of age], =>50 bpm for =>2 months to <12 months of age, or =>40 bpm for =>12 months to 24 months of age) or SpO2 <95% or chest wall indrawing. The causative pathogen was to be determined but may meet endpoint definition if RSV-positivity was confirmed per study requirements. Evaluable efficacy - infant population= all infant participants who were born to maternal participants who did not have major protocol deviations prior to the delivery and who received the investigational product to which they were randomized at least 14 days prior to delivery, were eligible, had no major protocol deviations. "Number of Participants Analyzed"= number of participants included in evaluable efficacy - infant population and evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Within 210, 240, 270 and 360 Days after birth

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was analysed only for infant participants.

End point values	Infant Participants: RSVpreF	Infant Participants: Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3495	3480		
Units: Percentage of cases				
number (not applicable)				
210 days after birth	2.0	3.6		
240 days after birth	2.2	3.8		
270 days after birth	2.3	3.9		
360 days after birth	2.6	4.5		

Statistical analyses

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy at 210 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	44.9
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	17.9
upper limit	63.5

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy at 360 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo

Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	41
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	16.2
upper limit	58.9

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy at 270 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	40.1
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	13
upper limit	59.2

Statistical analysis title	RSVpreF vs placebo

Statistical analysis description:

Vaccine efficacy at 240 days after birth. Vaccine efficacy was calculated as 1-(P/[1-P]), where P is the number of cases in the RSVpreF group divided by the total number of cases. The confidence interval was adjusted using Bonferroni procedure and accounting for the primary endpoints results. Vaccine efficacy was presented in percentage.

Comparison groups	Infant Participants: RSVpreF v Infant Participants: Placebo
Number of subjects included in analysis	6975
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Vaccine efficacy
Point estimate	42.9
Confidence interval	
level	Other: 99.17 %
sides	2-sided
lower limit	16.1
upper limit	61.6

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Maternal participants: AEs: Consent until 28 days after vaccination. SAEs & other AEs: Consent until end of study visit. Infant participants: AEs: Birth until 28 days after birth. SAEs, NDCMCs & other AEs: Consent until end of study visit

Adverse event reporting additional description:

LR & SE were assessed by systematic assessment (SA) & AEs by non-SA. Same event may appear as both an AE & SAE. But, what is presented are distinct events. An event may be categorized as serious in one participant & as non-serious in another, or a participant may have experienced both SAE & non-SAE Maternal & infant safety population was evaluated.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Maternal Participants: RSVpreF

Reporting group description:

Study-eligible pregnant women (maternal participants) were randomized to receive a single dose of 120 mcg RSVpreF, IM on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.

Reporting group title	Infant Participants: RSVpreF

Reporting group description:

Infant participants born to maternal participants vaccinated with a single dose of 120 mcg RSVpreF were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.

Reporting group title	Infant Participants: Placebo

Reporting group description:

Infant participants born to maternal participants who received placebo (matching RSVpreF without active vaccine) were included. Infant participants were all followed up for 12 months after birth, and for infants born to maternal participants during the first year of the study, they were followed up for 24 months after birth.

Reporting group title	Maternal Participants: Placebo

Reporting group description:

Maternal participants were randomized to receive placebo matching to RSVpreF as a single dose on Day 1 (day of vaccination). Participants were followed up to 6 months after delivery.

Serious adverse events	Maternal Participants: RSVpreF	Infant Participants: RSVpreF	Infant Participants: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	613 / 3698 (16.58%)	697 / 3659 (19.05%)	689 / 3646 (18.90%)
number of deaths (all causes)	1	8	14
number of deaths resulting from adverse events	1	8	14
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skull base tumour			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Spinal cord lipoma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Ovarian neoplasm			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Neuroblastoma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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 haemangioma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Neoplasm skin			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Haemangioma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma of skin			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Infantile haemangioma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 xanthogranuloma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Eyelid haemangioma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Kawasaki's disease			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Hypotension			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Blood pressure fluctuation			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cyanosis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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	13 / 3698 (0.35%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Superficial vein thrombosis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Scalp haematoma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Subgaleal haematoma			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Extradural haematoma evacuation			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Pregnancy, puerperium and perinatal conditions			
Low birth weight baby			
subjects affected / exposed	0 / 3698 (0.00%)	29 / 3659 (0.79%)	31 / 3646 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 29	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Postpartum haemorrhage			
subjects affected / exposed	29 / 3698 (0.78%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 29	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 3698 (0.00%)	49 / 3659 (1.34%)	42 / 3646 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 49	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Abnormal labour			
subjects affected / exposed	5 / 3698 (0.14%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion spontaneous			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Arrested labour			
subjects affected / exposed	37 / 3698 (1.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 37	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Birth trauma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Breech presentation			
subjects affected / exposed	6 / 3698 (0.16%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalhaematoma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cephalo-pelvic disproportion			
subjects affected / exposed	14 / 3698 (0.38%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal disorder			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Foetal death			
subjects affected / exposed	6 / 3698 (0.16%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal distress syndrome			
subjects affected / exposed	67 / 3698 (1.81%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 67	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delayed delivery			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Eclampsia			

subjects affected / exposed	7 / 3698 (0.19%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	1 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 presentation			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed induction of labour			
subjects affected / exposed	9 / 3698 (0.24%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed trial of labour			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
False labour			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Foetal growth restriction			
subjects affected / exposed	15 / 3698 (0.41%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	43 / 3698 (1.16%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 44	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational diabetes			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal-maternal haemorrhage			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
HELLP syndrome			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Foetal malpresentation			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Foetal malposition			
subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
Foetal macrosomia			
subjects affected / exposed	6 / 3698 (0.16%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal hypokinesia			
subjects affected / exposed	5 / 3698 (0.14%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal vascular malperfusion			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium in amniotic fluid			

subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
Large for dates baby			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Labour complication			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Jaundice neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	77 / 3659 (2.10%)	69 / 3646 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 79	0 / 69
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intrapartum haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic ischaemic encephalopathy neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hypothermia neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hydrops foetalis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Haemorrhage in pregnancy			

subjects affected / exposed	7 / 3698 (0.19%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meconium stain			
subjects affected / exposed	5 / 3698 (0.14%)	0 / 3659 (0.00%)	1 / 3646 (0.03%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripartum cardiomyopathy			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Oligohydramnios			
subjects affected / exposed	16 / 3698 (0.43%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 16	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructed labour			
subjects affected / exposed	15 / 3698 (0.41%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal disorder			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Precipitate labour			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 calcification			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Placental insufficiency			

subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Pre-eclampsia			
subjects affected / exposed	67 / 3698 (1.81%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 67	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placenta accreta			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Premature separation of placenta			
subjects affected / exposed	19 / 3698 (0.51%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	14 / 3698 (0.38%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 14	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	15 / 3698 (0.41%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	1 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature delivery			
subjects affected / exposed	30 / 3698 (0.81%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 30	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			

subjects affected / exposed	15 / 3698 (0.41%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained products of conception			
subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
Retained placenta or membranes			
subjects affected / exposed	8 / 3698 (0.22%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged rupture of membranes			
subjects affected / exposed	10 / 3698 (0.27%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged pregnancy			
subjects affected / exposed	9 / 3698 (0.24%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged labour			
subjects affected / exposed	23 / 3698 (0.62%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 23	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shoulder dystocia			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Small for dates baby			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	10 / 3646 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spontaneous rupture of membranes			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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	4 / 3698 (0.11%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord prolapse			
subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
Umbilical cord abnormality			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Transverse presentation			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Threatened labour			
subjects affected / exposed	15 / 3698 (0.41%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 18	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superimposed pre-eclampsia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 around neck			
subjects affected / exposed	1 / 3698 (0.03%)	3 / 3659 (0.08%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decrease neonatal			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Uterine atony			
subjects affected / exposed	5 / 3698 (0.14%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine hypotonus			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Uterine tachysystole			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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			
Death			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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 / 1
Sudden infant death syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Chills			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental delay			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Drug withdrawal syndrome neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	0 / 3646 (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
Fever neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Hypothermia			
subjects affected / exposed	0 / 3698 (0.00%)	4 / 3659 (0.11%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised oedema			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hypertrophy			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Mass			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Pyrexia			

subjects affected / exposed	2 / 3698 (0.05%)	2 / 3659 (0.05%)	8 / 3646 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrosomia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic reaction			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood type incompatibility			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Milk allergy			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Rhesus incompatibility			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Social circumstances			

Disease risk factor			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Female genital tract fistula			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Ovarian cyst			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	1 / 3646 (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
Ovarian cyst torsion			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 disorder			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Uterine prolapse			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine haemorrhage			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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

Uterine disorder			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Uterine cervix hyperplasia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 uterine rupture			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Testicular retraction			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 disorder			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Vulval haematoma			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Uterovaginal prolapse			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 discharge			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 haemorrhage			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3698 (0.00%)	4 / 3659 (0.11%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Meconium aspiration syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	9 / 3659 (0.25%)	7 / 3646 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Neonatal asphyxia			
subjects affected / exposed	0 / 3698 (0.00%)	8 / 3659 (0.22%)	7 / 3646 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pulmonary hypertension			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Asphyxia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Apnoea			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoidal hypertrophy			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	0 / 3646 (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
Acute respiratory failure			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Aspiration			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hypoxia			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choking			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Brief resolved unexplained event			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile apnoea			

subjects affected / exposed	0 / 3698 (0.00%)	10 / 3659 (0.27%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Nasal flaring			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Neonatal aspiration			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	11 / 3659 (0.30%)	14 / 3646 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 11	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress			
subjects affected / exposed	0 / 3698 (0.00%)	11 / 3659 (0.30%)	14 / 3646 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 11	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory depression			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Neonatal pneumothorax			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Neonatal hypoxia			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal dyspnoea			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Neonatal respiratory failure			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Pulmonary artery stenosis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Pneumothorax spontaneous			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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 / 3698 (0.00%)	5 / 3659 (0.14%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis aspiration			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Pneumomediastinum			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstructive sleep apnoea syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Neonatal tachypnoea			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Pulmonary haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Respiration abnormal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 3698 (0.00%)	33 / 3659 (0.90%)	29 / 3646 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 33	0 / 29
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachypnoea			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	8 / 3646 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	0 / 3698 (0.00%)	49 / 3659 (1.34%)	46 / 3646 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 49	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory disorder neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory depression			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Respiratory acidosis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Psychiatric disorders			
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brief psychotic disorder, with postpartum onset			

subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Depression			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 self-injury			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Panic attack			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Selective eating disorder			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Perinatal depression			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Panic disorder			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Product issues			
Device occlusion			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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			
Chronic hepatic failure			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hepatic haematoma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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 / 1
Hepatic function abnormal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder polyp			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Cholestasis of pregnancy			
subjects affected / exposed	11 / 3698 (0.30%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis			
subjects affected / exposed	2 / 3698 (0.05%)	1 / 3659 (0.03%)	0 / 3646 (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
Cholelithiasis			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Cholecystitis acute			

subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Biliary obstruction			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Biliary colic			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stone			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Neonatal cholestasis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Jaundice			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hypertransaminasaemia			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	51 / 3659 (1.39%)	42 / 3646 (1.15%)
occurrences causally related to treatment / all	0 / 0	0 / 51	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Hepatitis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Intrahepatic portal hepatic venous fistula			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Investigations			
Blood glucose decreased			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 glucose			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Blood bilirubin increased			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Base excess decreased			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Apgar score low			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Amniotic fluid volume decreased			

subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Body temperature fluctuation			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Body temperature increased			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Cytomegalovirus test positive			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiogram abnormal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiovascular function test abnormal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Cardiac murmur			
subjects affected / exposed	1 / 3698 (0.03%)	4 / 3659 (0.11%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation abnormal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Foetal heart rate indeterminate			

subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Foetal monitoring abnormal			
subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
HIV test positive			
subjects affected / exposed	1 / 3698 (0.03%)	1 / 3659 (0.03%)	0 / 3646 (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
Nutritional condition abnormal			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	0 / 3646 (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
Foetal heart rate abnormal			
subjects affected / exposed	7 / 3698 (0.19%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcus test positive			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
SARS-CoV-2 test positive			
subjects affected / exposed	5 / 3698 (0.14%)	0 / 3659 (0.00%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Oxygen saturation decreased			

subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ultrasound antenatal screen abnormal			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
White blood cell count increased			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Weight decreased			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Ultrasound foetal abnormal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal injury			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Ankle fracture			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Bladder injury			

subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Burns second degree			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Fall			
subjects affected / exposed	1 / 3698 (0.03%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Exposure to SARS-CoV-2			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Extradural haematoma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Concussion			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Foetal exposure during pregnancy			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Forearm fracture			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body in respiratory tract			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Foreign body ingestion			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fractured skull depressed			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hand fracture			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Injury to brachial plexus due to birth trauma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Joint injury			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Maternal drugs affecting foetus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 3698 (0.00%)	4 / 3659 (0.11%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal injury			
subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
Procedural headache			

subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Postoperative ileus			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 procedural fever			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Post lumbar puncture syndrome			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Road traffic accident			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Vulvovaginal injury			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Vascular procedure complication			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine rupture			

subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
Traumatic intracranial haematoma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 / 3698 (0.00%)	4 / 3659 (0.11%)	1 / 3646 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Congenital, familial and genetic disorders			
Inborn error of metabolism			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Ventricular hypoplasia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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 / 1
Aberrant aortic arch			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accessory spleen			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Autosomal chromosome anomaly			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Atrioventricular septal defect			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Atrial septal defect			
subjects affected / exposed	0 / 3698 (0.00%)	37 / 3659 (1.01%)	46 / 3646 (1.26%)
occurrences causally related to treatment / all	0 / 0	0 / 39	0 / 49
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicuspid aortic valve			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	0 / 3646 (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
Anorchism			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Anomaly of external ear congenital			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Anisomelia			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal atresia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Anorectal malformation			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Bifid ureter			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Brachycephaly			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Branchial cyst			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Buried penis syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Cleft uvula			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Chordee			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chromosomal deletion			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Cleft lip and palate			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Cleft palate			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract congenital			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Coarctation of the aorta			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coloboma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital absence of bile ducts			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Congenital aortic anomaly			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital foot malformation			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital coronary artery malformation			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital cytomegalovirus infection			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Congenital diaphragmatic eventration			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Congenital eye disorder			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital central nervous system anomaly			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Congenital hydronephrosis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital hypothyroidism			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital knee deformity			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital megacolon			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Congenital retinoblastoma			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital musculoskeletal disorder			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Congenital musculoskeletal disorder of spine			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital naevus			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Congenital pulmonary artery anomaly			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Congenital melanocytic naevus			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Congenital skin dimples			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital syphilis			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	1 / 3646 (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
Congenital torticollis			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Congenital urethral anomaly			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Developmental hip dysplasia			
subjects affected / exposed	0 / 3698 (0.00%)	11 / 3659 (0.30%)	15 / 3646 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 11	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniosynostosis			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	1 / 3646 (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
Cryptorchism			
subjects affected / exposed	0 / 3698 (0.00%)	12 / 3659 (0.33%)	18 / 3646 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 12	0 / 18
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystic fibrosis			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Deafness congenital			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Craniofacial deformity			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Dextrocardia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Dolichocephaly			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Duane's syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Dysmorphism			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Genitalia external ambiguous			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Eyelid ptosis congenital			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Galactosaemia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Gallbladder anomaly congenital			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Ear malformation			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Haemangioma congenital			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hypoplastic left heart syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hypospadias			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	11 / 3646 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal malrotation			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Left-to-right cardiac shunt			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Kidney duplex			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Laryngeal cleft			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Laryngomalacia			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	1 / 3646 (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
Iris coloboma			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Microphthalmos			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Mitochondrial encephalomyopathy			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Naevus flammeus			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Neurofibromatosis			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Micropenis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Macrocephaly			
subjects affected / exposed	0 / 3698 (0.00%)	5 / 3659 (0.14%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningocele			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Microcephaly			
subjects affected / exposed	0 / 3698 (0.00%)	7 / 3659 (0.19%)	7 / 3646 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micrognathia			
subjects affected / exposed	0 / 3698 (0.00%)	5 / 3659 (0.14%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb reduction defect			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Newborn persistent pulmonary hypertension			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal atresia			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Optic nerve hypoplasia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Osteochondrodysplasia			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Patent ductus arteriosus			
subjects affected / exposed	0 / 3698 (0.00%)	13 / 3659 (0.36%)	14 / 3646 (0.38%)
occurrences causally related to treatment / all	0 / 0	0 / 13	0 / 14
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pectus excavatum			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penile torsion			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Penoscrotal fusion			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phenylketonuria			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Phimosis			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Plagiocephaly			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poland's syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Polycystic liver disease			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Polydactyly			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	7 / 3646 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal aplasia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preternatural anus			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Pulmonary artery stenosis congenital			
subjects affected / exposed	0 / 3698 (0.00%)	7 / 3659 (0.19%)	6 / 3646 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyloric stenosis			

subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	1 / 3646 (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
Pyruvate carboxylase deficiency			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Posterior segment of eye anomaly congenital			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Renal dysplasia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 tract hypoplasia, male			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Scaphocephaly			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Septo-optic dysplasia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Thalassaemia alpha			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Supernumerary nipple			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Syndactyly			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Talipes			
subjects affected / exposed	0 / 3698 (0.00%)	5 / 3659 (0.14%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tethered oral tissue			
subjects affected / exposed	0 / 3698 (0.00%)	18 / 3659 (0.49%)	16 / 3646 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 18	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spina bifida occulta			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Trisomy 21			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vallecular cyst			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular malformation			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Ventricular septal defect			

subjects affected / exposed	0 / 3698 (0.00%)	15 / 3659 (0.41%)	21 / 3646 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 15	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Left ventricular failure			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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 / 1
Atrioventricular block first degree			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Atrioventricular block complete			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Bradycardia			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	1 / 3646 (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
Bradycardia foetal			
subjects affected / exposed	8 / 3698 (0.22%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Foetal arrhythmia			

subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Foetal heart rate deceleration abnormality			
subjects affected / exposed	6 / 3698 (0.16%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic left ventricular failure			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 ventricular disorder			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Cardiac failure			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery dissection			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Pulmonary valve stenosis			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary valve thickening			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Right atrial enlargement			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 arrhythmia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 bradycardia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Left ventricular hypertrophy			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Mitral valve incompetence			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	1 / 3646 (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
Neonatal bradyarrhythmia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nonreassuring foetal heart rate pattern			
subjects affected / exposed	37 / 3698 (1.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 37	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			

subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Supraventricular extrasystoles			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Ventricular extrasystoles			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve disease			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Tachycardia foetal			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Tachycardia			
subjects affected / exposed	4 / 3698 (0.11%)	0 / 3659 (0.00%)	1 / 3646 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cerebral cyst			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	0 / 3646 (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
Atypical migraine			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 enlargement of the subarachnoid spaces			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Cerebral ventricle dilatation			
subjects affected / exposed	0 / 3698 (0.00%)	5 / 3659 (0.14%)	1 / 3646 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Depressed level of consciousness			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 / 3698 (0.00%)	9 / 3659 (0.25%)	13 / 3646 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
External hydrocephalus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Encephalomalacia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hemiparesis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hydrocephalus			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hyporeflexia			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hypotonia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Headache			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Intraventricular haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Intraventricular haemorrhage neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lenticulostriatal vasculopathy			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Intracranial haemorrhage neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Lumbar radiculopathy			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Motor developmental delay			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Moyamoya disease			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myoclonus			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Quadriparesis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Non-epileptic paroxysmal event			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Nystagmus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Paraplegia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Neurodevelopmental delay			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Seizure			

subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	6 / 3646 (0.16%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech disorder developmental			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Spinal cord compression			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Status epilepticus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Tethered cord syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 haemorrhage neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Subependymal cyst			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Subarachnoid haemorrhage			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Tremor			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 and lymphatic system disorders			
Hypochromic anaemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Anaemia neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Anaemia of pregnancy			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood loss anaemia			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Haemolysis neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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			
subjects affected / exposed	4 / 3698 (0.11%)	1 / 3659 (0.03%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic neutropenia			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Iron deficiency anaemia			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	1 / 3646 (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
Neutropenia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Polycythaemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Splenic cyst			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Thrombocytopenia			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia neonatorum			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Eustachian tube dysfunction			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Hypoacusis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Tympanic membrane perforation			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Deafness			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Pupillary disorder			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Eyelid ptosis			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Eye haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Gastrointestinal disorders			
Food protein-induced enterocolitis syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal pain			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 lower			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Crohn's disease			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Diaphragmatic hernia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Diarrhoea			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	1 / 3698 (0.03%)	1 / 3659 (0.03%)	0 / 3646 (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
Constipation			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile colic			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Infantile vomiting			
subjects affected / exposed	0 / 3698 (0.00%)	4 / 3659 (0.11%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	8 / 3646 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	1 / 3646 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal ulcer			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Intussusception			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable bowel syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Meconium ileus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 pancreatitis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising colitis			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Obstruction gastric			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Meconium plug syndrome			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Tongue disorder			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Terminal ileitis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Skin and subcutaneous tissue disorders			
Petechiae			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Eczema			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermal cyst			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Scar pain			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash vesicular			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Rash neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Rash			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 bladder			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Haematuria			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 / 3698 (0.00%)	6 / 3659 (0.16%)	8 / 3646 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hydronephrosis			
subjects affected / exposed	1 / 3698 (0.03%)	6 / 3659 (0.16%)	9 / 3646 (0.25%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydroureter			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Kidney small			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Neonatal anuria			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Nephrectasia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Nephrolithiasis			
subjects affected / exposed	3 / 3698 (0.08%)	0 / 3659 (0.00%)	0 / 3646 (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
Prerenal failure			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Vesicoureteric reflux			

subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterocele			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Ureteric dilatation			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 impairment			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 retention			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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			
Hypopituitarism			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Musculoskeletal and connective tissue disorders			
Diastasis recti abdominis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Arthralgia			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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

Ankle deformity			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Acquired plagiocephaly			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Facial asymmetry			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Joint instability			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 deformity			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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 deformity			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Flank pain			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Pain in extremity			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Knee deformity			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Kyphosis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Limb deformity			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 spasms			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 noise			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Seronegative arthritis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Sacroiliitis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Retrognathia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Posture abnormal			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Torticollis			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	7 / 3646 (0.19%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Escherichia sepsis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Gastroenteritis			
subjects affected / exposed	5 / 3698 (0.14%)	23 / 3659 (0.63%)	18 / 3646 (0.49%)
occurrences causally related to treatment / all	0 / 5	0 / 25	0 / 20
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Sepsis neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	19 / 3659 (0.52%)	21 / 3646 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 19	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Pneumonia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Amniotic cavity infection			
subjects affected / exposed	10 / 3698 (0.27%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 10	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Abscess oral			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Adenovirus infection			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Amoebic dysentery			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Appendicitis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 bacterial			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Bacterial infection			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast abscess			
subjects affected / exposed	1 / 3698 (0.03%)	1 / 3659 (0.03%)	0 / 3646 (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
Bacterial sepsis			

subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	0 / 3646 (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
Bacteriuria			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Botulism			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Bacterial pyelonephritis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
COVID-19			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 3698 (0.03%)	3 / 3659 (0.08%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Chest wall abscess			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 bacterial			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Endometritis			
subjects affected / exposed	5 / 3698 (0.14%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	1 / 3646 (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
Diverticulitis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Ear infection			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Encephalitis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Dacryocystitis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Epididymitis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 bacteraemia			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Escherichia urinary tract infection			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	0 / 3646 (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
Exanthema subitum			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Groin abscess			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Gastroenteritis Escherichia coli			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Infection			
subjects affected / exposed	0 / 3698 (0.00%)	14 / 3659 (0.38%)	15 / 3646 (0.41%)
occurrences causally related to treatment / all	0 / 0	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Meningitis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Kidney infection			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Klebsiella sepsis			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Klebsiella urinary tract infection			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Mastitis			
subjects affected / exposed	5 / 3698 (0.14%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral discitis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Meningitis bacterial			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis cronobacter			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Meningitis enteroviral			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Meningitis streptococcal			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Ophthalmia neonatorum			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Neonatal infection			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal infective mastitis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Neonatal pneumonia			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	1 / 3646 (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
Omphalitis			
subjects affected / exposed	0 / 3698 (0.00%)	4 / 3659 (0.11%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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 / 3698 (0.00%)	3 / 3659 (0.08%)	0 / 3646 (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
Otitis media chronic			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Pilonidal disease			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Perirectal abscess			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Peritonitis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Pathogen resistance			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Postpartum sepsis			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Puerperal infection			

subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Puerperal pyrexia			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 3698 (0.03%)	2 / 3659 (0.05%)	3 / 3646 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Pyomyositis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Pneumococcal bacteraemia			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 procedural infection			
subjects affected / exposed	2 / 3698 (0.05%)	0 / 3659 (0.00%)	0 / 3646 (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
Postoperative abscess			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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 / 3698 (0.00%)	3 / 3659 (0.08%)	1 / 3646 (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
Pyuria			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Salmonellosis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Secondary syphilis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
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	1 / 3698 (0.03%)	9 / 3659 (0.25%)	4 / 3646 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 9	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal skin infection			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Skin infection			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Staphylococcal scalded skin syndrome			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	1 / 3698 (0.03%)	1 / 3659 (0.03%)	0 / 3646 (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
Septic coagulopathy			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Tinea versicolour			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Tooth abscess			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Tooth infection			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Wound sepsis			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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	7 / 3698 (0.19%)	15 / 3659 (0.41%)	14 / 3646 (0.38%)
occurrences causally related to treatment / all	0 / 7	0 / 15	0 / 15
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acidosis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Dehydration			
subjects affected / exposed	0 / 3698 (0.00%)	9 / 3659 (0.25%)	13 / 3646 (0.36%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Electrolyte imbalance			

subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hyperkalaemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Food aversion			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Fluid intake reduced			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Feeding intolerance			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Feeding disorder			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Failure to thrive			
subjects affected / exposed	0 / 3698 (0.00%)	6 / 3659 (0.16%)	5 / 3646 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	13 / 3659 (0.36%)	10 / 3646 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 13	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	1 / 3698 (0.03%)	0 / 3659 (0.00%)	0 / 3646 (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
Hypovolaemia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Lactose intolerance			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hypernatraemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Hyperphosphataemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Hypervolaemia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Hypocalcaemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Hypoglycaemia			

subjects affected / exposed	0 / 3698 (0.00%)	20 / 3659 (0.55%)	17 / 3646 (0.47%)
occurrences causally related to treatment / all	0 / 0	0 / 20	0 / 17
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malnutrition			
subjects affected / exposed	0 / 3698 (0.00%)	2 / 3659 (0.05%)	1 / 3646 (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
Metabolic acidosis			
subjects affected / exposed	0 / 3698 (0.00%)	3 / 3659 (0.08%)	2 / 3646 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal hyponatraemia			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (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
Poor feeding infant			
subjects affected / exposed	0 / 3698 (0.00%)	0 / 3659 (0.00%)	1 / 3646 (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
Weight gain poor			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	1 / 3646 (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
Underweight			
subjects affected / exposed	0 / 3698 (0.00%)	1 / 3659 (0.03%)	0 / 3646 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Maternal Participants: Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	581 / 3687 (15.76%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skull base tumour			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord lipoma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian neoplasm			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuroblastoma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye haemangioma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm skin			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemangioma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Haemangioma of skin				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infantile haemangioma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Juvenile xanthogranuloma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eyelid haemangioma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulcerated haemangioma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Kawasaki's disease				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypovolaemic shock				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood pressure fluctuation				

subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cyanosis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Haemorrhage				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	6 / 3687 (0.16%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Superficial vein thrombosis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scalp haematoma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subgaleal haematoma				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Extradural haematoma evacuation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Low birth weight baby			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum haemorrhage			
subjects affected / exposed	33 / 3687 (0.90%)		
occurrences causally related to treatment / all	0 / 33		
deaths causally related to treatment / all	0 / 0		
Premature baby			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abnormal labour			
subjects affected / exposed	7 / 3687 (0.19%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Arrested labour			
subjects affected / exposed	43 / 3687 (1.17%)		
occurrences causally related to treatment / all	0 / 43		
deaths causally related to treatment / all	0 / 0		

Birth trauma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breech presentation			
subjects affected / exposed	5 / 3687 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Cephalhaematoma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cephalo-pelvic disproportion			
subjects affected / exposed	19 / 3687 (0.52%)		
occurrences causally related to treatment / all	0 / 19		
deaths causally related to treatment / all	0 / 0		
Foetal disorder			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Foetal death			
subjects affected / exposed	8 / 3687 (0.22%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Foetal distress syndrome			
subjects affected / exposed	65 / 3687 (1.76%)		
occurrences causally related to treatment / all	0 / 65		
deaths causally related to treatment / all	0 / 0		
Delayed delivery			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eclampsia			

subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ectopic pregnancy			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Face presentation			
subjects affected / exposed	4 / 3687 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Failed induction of labour			
subjects affected / exposed	8 / 3687 (0.22%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Failed trial of labour			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
False labour			
subjects affected / exposed	5 / 3687 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Foetal growth restriction			
subjects affected / exposed	11 / 3687 (0.30%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension			
subjects affected / exposed	41 / 3687 (1.11%)		
occurrences causally related to treatment / all	0 / 41		
deaths causally related to treatment / all	0 / 0		
Gestational diabetes			

subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foetal-maternal haemorrhage				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
HELLP syndrome				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Foetal malpresentation				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal malposition				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foetal macrosomia				
subjects affected / exposed	7 / 3687 (0.19%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Foetal hypokinesia				
subjects affected / exposed	4 / 3687 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Foetal vascular malperfusion				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meconium in amniotic fluid				

subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Large for dates baby			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Labour complication			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Jaundice neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intrapartum haemorrhage			
subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hypoxic ischaemic encephalopathy neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothermia neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrops foetalis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage in pregnancy			

subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Meconium stain			
subjects affected / exposed	5 / 3687 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Peripartum cardiomyopathy			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Oligohydramnios			
subjects affected / exposed	21 / 3687 (0.57%)		
occurrences causally related to treatment / all	0 / 21		
deaths causally related to treatment / all	0 / 0		
Obstructed labour			
subjects affected / exposed	12 / 3687 (0.33%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Neonatal disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Precipitate labour			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Placental calcification			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental insufficiency			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polyhydramnios			
subjects affected / exposed	4 / 3687 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	53 / 3687 (1.44%)		
occurrences causally related to treatment / all	0 / 53		
deaths causally related to treatment / all	0 / 0		
Placenta accreta			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Premature separation of placenta			
subjects affected / exposed	13 / 3687 (0.35%)		
occurrences causally related to treatment / all	1 / 13		
deaths causally related to treatment / all	0 / 0		
Premature rupture of membranes			
subjects affected / exposed	16 / 3687 (0.43%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Premature labour			
subjects affected / exposed	9 / 3687 (0.24%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Premature delivery			
subjects affected / exposed	24 / 3687 (0.65%)		
occurrences causally related to treatment / all	0 / 24		
deaths causally related to treatment / all	0 / 0		
Preterm premature rupture of membranes			

subjects affected / exposed	11 / 3687 (0.30%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Retained products of conception			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Retained placenta or membranes			
subjects affected / exposed	5 / 3687 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Prolonged rupture of membranes			
subjects affected / exposed	10 / 3687 (0.27%)		
occurrences causally related to treatment / all	0 / 10		
deaths causally related to treatment / all	0 / 0		
Prolonged pregnancy			
subjects affected / exposed	7 / 3687 (0.19%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Prolonged labour			
subjects affected / exposed	21 / 3687 (0.57%)		
occurrences causally related to treatment / all	0 / 21		
deaths causally related to treatment / all	0 / 0		
Shoulder dystocia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small for dates baby			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spontaneous rupture of membranes			

subjects affected / exposed	2 / 3687 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Stillbirth				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical cord prolapse				
subjects affected / exposed	4 / 3687 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Umbilical cord abnormality				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transverse presentation				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Threatened labour				
subjects affected / exposed	14 / 3687 (0.38%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Superimposed pre-eclampsia				
subjects affected / exposed	2 / 3687 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Umbilical cord around neck				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decrease neonatal				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine atony				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Uterine contractions during pregnancy				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Uterine hypotonus				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine tachysystole				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Death				
subjects affected / exposed	0 / 3687 (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 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden infant death syndrome				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chills				

subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Developmental delay				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug withdrawal syndrome neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fever neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypothermia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Localised oedema				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertrophy				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mass				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				

subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Macrosomia			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaphylactic reaction			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood type incompatibility			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypogammaglobulinaemia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Milk allergy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhesus incompatibility			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Social circumstances			

Disease risk factor				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Intermenstrual bleeding				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Female genital tract fistula				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian cyst torsion				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Perineal disorder				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine prolapse				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine haemorrhage				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Uterine disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine cervix hyperplasia			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Threatened uterine rupture			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Testicular torsion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Testicular retraction			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Testicular disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vulval haematoma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterovaginal prolapse			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vaginal discharge			

subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vaginal haemorrhage				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Dyspnoea				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meconium aspiration syndrome				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal asphyxia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary hypertension				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asphyxia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Apnoea				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenoidal hypertrophy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute respiratory failure			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspiration			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Choking			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brief resolved unexplained event			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infantile apnoea			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal flaring			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal aspiration			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory distress syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory distress			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory depression			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal pneumothorax			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal hypoxia			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal dyspnoea			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory failure			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pulmonary artery stenosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary arterial hypertension			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax spontaneous			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonitis aspiration			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumomediastinum				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obstructive sleep apnoea syndrome				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal tachypnoea				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary haemorrhage				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiration abnormal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient tachypnoea of the newborn				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachypnoea				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sleep apnoea syndrome				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory disorder neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory depression				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory acidosis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Attention deficit hyperactivity disorder				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bipolar disorder				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brief psychotic disorder, with postpartum onset				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anxiety disorder				
subjects affected / exposed	0 / 3687 (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 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Panic attack				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Selective eating disorder				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perinatal depression				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Panic disorder				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Product issues				
Device occlusion				

subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Chronic hepatic failure			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic haematoma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic function abnormal			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gallbladder polyp			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholestasis of pregnancy			
subjects affected / exposed	6 / 3687 (0.16%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Cholestasis			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			

subjects affected / exposed	2 / 3687 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Biliary obstruction				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biliary colic				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bile duct stone				
subjects affected / exposed	4 / 3687 (0.11%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Neonatal cholestasis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertransaminasaemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intrahepatic portal hepatic venous fistula				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood glucose decreased				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood glucose				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Base excess decreased				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Apgar score low				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amniotic fluid volume decreased				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Body temperature fluctuation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Body temperature increased			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytomegalovirus test positive			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholangiogram abnormal			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiovascular function test abnormal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac murmur			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oxygen saturation abnormal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal heart rate indeterminate			

subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foetal monitoring abnormal				
subjects affected / exposed	6 / 3687 (0.16%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
HIV test positive				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nutritional condition abnormal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foetal heart rate abnormal				
subjects affected / exposed	2 / 3687 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Streptococcus test positive				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
SARS-CoV-2 test positive				
subjects affected / exposed	2 / 3687 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oxygen saturation decreased				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ultrasound antenatal screen abnormal				
subjects affected / exposed	2 / 3687 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
White blood cell count increased				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decreased				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ultrasound foetal abnormal				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Accidental exposure to product				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal injury				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder injury				

subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Burns second degree			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniocerebral injury			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Electrical burn			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exposure to SARS-CoV-2			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extradural haematoma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal exposure during pregnancy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Forearm fracture			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body in respiratory tract			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foreign body ingestion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fractured skull depressed			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hand fracture			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury to brachial plexus due to birth trauma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint injury				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Maternal drugs affecting foetus				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fractured base				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perineal injury				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Procedural headache				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative ileus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural fever			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vulvovaginal injury			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular procedure complication			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine rupture			

subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Traumatic intracranial haematoma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thermal burn				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tendon rupture				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Subdural haemorrhage				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haematoma				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Inborn error of metabolism				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular hypoplasia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aberrant aortic arch				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Accessory spleen				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autosomal chromosome anomaly				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrioventricular septal defect				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial septal defect				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bicuspid aortic valve				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anorchism				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anomaly of external ear congenital				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anisomelia				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal atresia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anorectal malformation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bifid ureter			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brachycephaly			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Branchial cyst			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Buried penis syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cleft uvula			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chordee			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chromosomal deletion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cleft lip and palate			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cleft palate			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cataract congenital			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coarctation of the aorta			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coloboma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital absence of bile ducts			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital aortic anomaly			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital foot malformation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital coronary artery malformation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital cytomegalovirus infection			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital diaphragmatic eventration			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital eye disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital central nervous system anomaly			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital hydronephrosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital hypothyroidism			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital knee deformity			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital megacolon			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital retinoblastoma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital musculoskeletal disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital musculoskeletal disorder of spine			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital naevus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital pulmonary artery anomaly			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital melanocytic naevus			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital skin dimples			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital syphilis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital torticollis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital urethral anomaly			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Developmental hip dysplasia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniosynostosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cryptorchism			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystic fibrosis			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deafness congenital				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Craniofacial deformity				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dextrocardia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dolichocephaly				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Duane's syndrome				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysmorphism				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genitalia external ambiguous				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eyelid ptosis congenital				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Galactosaemia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gallbladder anomaly congenital			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear malformation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemangioma congenital			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoplastic left heart syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypospadias			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal malrotation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left-to-right cardiac shunt			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney duplex			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngeal cleft			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngomalacia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iris coloboma			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Microphthalmos			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitochondrial encephalomyopathy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Naevus flammeus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neurofibromatosis			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Micropenis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Macrocephaly				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningocele				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Microcephaly				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Micrognathia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Limb reduction defect				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Newborn persistent pulmonary hypertension				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal atresia				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Optic nerve hypoplasia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteochondrodysplasia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Patent ductus arteriosus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pectus excavatum			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penile torsion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penoscrotal fusion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phenylketonuria			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phimosis			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Plagiocephaly				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Poland's syndrome				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polycystic liver disease				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polydactyly				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal aplasia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Preternatural anus				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary artery stenosis congenital				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyloric stenosis				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyruvate carboxylase deficiency			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Posterior segment of eye anomaly congenital			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal dysplasia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive tract hypoplasia, male			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Scaphocephaly			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septo-optic dysplasia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thalassaemia alpha			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supernumerary nipple			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syndactyly			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Talipes			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tethered oral tissue			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spina bifida occulta			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trisomy 21			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vallecular cyst			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular malformation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular septal defect			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block first degree			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrioventricular block complete			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bradycardia foetal			
subjects affected / exposed	13 / 3687 (0.35%)		
occurrences causally related to treatment / all	0 / 13		
deaths causally related to treatment / all	0 / 0		
Bradycardia neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal arrhythmia			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal heart rate deceleration abnormality			
subjects affected / exposed	12 / 3687 (0.33%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Chronic left ventricular failure			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac ventricular disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery dissection			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pericardial effusion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary valve stenosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary valve thickening			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Right atrial enlargement			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus arrhythmia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus bradycardia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Left ventricular hypertrophy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mitral valve incompetence			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal bradyarrhythmia			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nonreassuring foetal heart rate pattern			
subjects affected / exposed	30 / 3687 (0.81%)		
occurrences causally related to treatment / all	0 / 30		
deaths causally related to treatment / all	0 / 0		
Sinus tachycardia			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular extrasystoles			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular extrasystoles			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve disease			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia foetal			
subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Tachycardia			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral cyst			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atypical migraine			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Benign enlargement of the subarachnoid spaces			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ventricle dilatation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depressed level of consciousness			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalopathy neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
External hydrocephalus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalomalacia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hemiparesis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocephalus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyporeflexia			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotonia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Intraventricular haemorrhage			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intraventricular haemorrhage neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lenticulostriatal vasculopathy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial haemorrhage neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Motor developmental delay			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Moyamoya disease			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myoclonus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Quadriparesis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-epileptic paroxysmal event			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nystagmus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraplegia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neurodevelopmental delay			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Speech disorder developmental			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal cord compression			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Status epilepticus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tethered cord syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haemorrhage neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subependymal cyst			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage			

subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tremor				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Hypochromic anaemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia of pregnancy				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood loss anaemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemolysis neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	5 / 3687 (0.14%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Idiopathic neutropenia				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Iron deficiency anaemia				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polycythaemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Splenic cyst				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polycythaemia neonatorum				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Deafness unilateral				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eustachian tube dysfunction				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoacusis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tympanic membrane perforation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deafness			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Pupillary disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eyelid ptosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye haemorrhage			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Food protein-induced enterocolitis syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abdominal pain			
subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Crohn's disease			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diaphragmatic hernia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enterocolitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infantile colic			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infantile vomiting			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematemesis			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileal ulcer			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intussusception			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Irritable bowel syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meconium ileus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructive pancreatitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			

subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Necrotising colitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstruction gastric			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meconium plug syndrome			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tongue disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			

subjects affected / exposed	2 / 3687 (0.05%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Terminal ileitis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Petechiae				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eczema				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermal cyst				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pruritus				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seborrhoeic dermatitis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scar pain				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rash vesicular				

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 3687 (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	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Calculus bladder				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematuria				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal colic				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelocaliectasis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal cyst				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hydroureter			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney small			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal anuria			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrectasia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prerenal failure			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vesicoureteric reflux			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureterocele			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureteric dilatation			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hypopituitarism			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Diastasis recti abdominis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Ankle deformity				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acquired plagiocephaly				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial asymmetry				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint instability				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head deformity				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Foot deformity				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Knee deformity				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kyphosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb deformity			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle spasms			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint noise			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seronegative arthritis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sacroiliitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retrognathia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Posture abnormal			

subjects affected / exposed	0 / 3687 (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 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Torticollis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Escherichia sepsis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	3 / 3687 (0.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Sepsis neonatal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amniotic cavity infection				
subjects affected / exposed	5 / 3687 (0.14%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Abscess limb				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abscess oral			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenovirus infection			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amoebic dysentery			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast abscess			
subjects affected / exposed	4 / 3687 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Bacterial sepsis			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteriuria				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Botulism				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial pyelonephritis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis staphylococcal				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chest wall abscess				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Conjunctivitis bacterial				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometritis			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear infection			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dacryocystitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epididymitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia			

subjects affected / exposed	0 / 3687 (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 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exanthema subitum			
subjects affected / exposed	0 / 3687 (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 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Groin abscess			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis Escherichia coli			

subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Impetigo				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infectious mononucleosis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Kidney infection				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Klebsiella sepsis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Klebsiella urinary tract infection				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastitis			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral discitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis bacterial			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis cronobacter			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis enteroviral			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis streptococcal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ophthalmia neonatorum			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal infection			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal infective mastitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal pneumonia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Omphalitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	0 / 3687 (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 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media chronic			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pilonidal disease				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pelvic abscess				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Periorbital cellulitis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Perirectal abscess				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pathogen resistance				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postpartum sepsis				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Puerperal infection				

subjects affected / exposed	3 / 3687 (0.08%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Puerperal pyrexia			
subjects affected / exposed	2 / 3687 (0.05%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	4 / 3687 (0.11%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	5 / 3687 (0.14%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Pyomyositis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumococcal bacteraemia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural infection			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative abscess			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			

subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyuria			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Salmonellosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Secondary syphilis			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal skin infection			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal scalded skin syndrome			

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Staphylococcal sepsis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic coagulopathy			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tinea versicolour			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tooth infection			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	1 / 3687 (0.03%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral infection			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound sepsis				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	6 / 3687 (0.16%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Decreased appetite				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acidosis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetes mellitus				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electrolyte imbalance				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food aversion			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fluid intake reduced			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Feeding intolerance			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Feeding disorder			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			

subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypovolaemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lactose intolerance				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypernatraemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperphosphataemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypervolaemia				
subjects affected / exposed	1 / 3687 (0.03%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypoalbuminaemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypocalcaemia				
subjects affected / exposed	0 / 3687 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				

subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malnutrition			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal hyponatraemia			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Poor feeding infant			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight gain poor			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Underweight			
subjects affected / exposed	0 / 3687 (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: 1 %

Non-serious adverse events	Maternal Participants: RSVpreF	Infant Participants: RSVpreF	Infant Participants: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2755 / 3698 (74.50%)	674 / 3659 (18.42%)	598 / 3646 (16.40%)
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	148 / 3698 (4.00%)	119 / 3659 (3.25%)	108 / 3646 (2.96%)
occurrences (all)	148	122	111
Congenital, familial and genetic disorders			
Tethered oral tissue			
subjects affected / exposed	0 / 3698 (0.00%)	41 / 3659 (1.12%)	32 / 3646 (0.88%)
occurrences (all)	0	41	32
Congenital naevus			
subjects affected / exposed	0 / 3698 (0.00%)	49 / 3659 (1.34%)	30 / 3646 (0.82%)
occurrences (all)	0	49	30
Nervous system disorders			
Headache (HEADACHE)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[1]	1141 / 3678 (31.02%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Pregnancy, puerperium and perinatal conditions			
Premature delivery			
subjects affected / exposed	182 / 3698 (4.92%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	182	0	0
Premature baby			
subjects affected / exposed	0 / 3698 (0.00%)	158 / 3659 (4.32%)	130 / 3646 (3.57%)
occurrences (all)	0	158	130
Low birth weight baby			
subjects affected / exposed	0 / 3698 (0.00%)	157 / 3659 (4.29%)	127 / 3646 (3.48%)
occurrences (all)	0	157	127
Jaundice neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	191 / 3659 (5.22%)	183 / 3646 (5.02%)
occurrences (all)	0	193	185
General disorders and administration site conditions			

Swelling (SWELLING)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	228 / 3678 (6.20%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Injection site pain (PAIN AT INJECTION SITE)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[3]	1496 / 3678 (40.67%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Fatigue (FATIGUE)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[4]	1696 / 3678 (46.11%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Pyrexia (FEVER)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[5]	94 / 3678 (2.56%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Gastrointestinal disorders			
Vomiting (VOMITING)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[6]	289 / 3678 (7.86%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Nausea (NAUSEA)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[7]	734 / 3678 (19.96%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Diarrhoea (DIARRHEA)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			

subjects affected / exposed[8]	414 / 3678 (11.26%)	0 / 3569 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 3698 (0.00%)	59 / 3659 (1.61%)	65 / 3646 (1.78%)
occurrences (all)	0	59	65
Skin and subcutaneous tissue disorders			
Erythema (REDNESS)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[9]	265 / 3678 (7.21%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 3698 (0.00%)	31 / 3659 (0.85%)	39 / 3646 (1.07%)
occurrences (all)	0	31	39
Musculoskeletal and connective tissue disorders			
Myalgia (MUSCLE PAIN)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[10]	977 / 3678 (26.56%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0
Arthralgia (JOINT PAIN)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[11]	426 / 3678 (11.58%)	0 / 3659 (0.00%)	0 / 3646 (0.00%)
occurrences (all)	99999	0	0

Non-serious adverse events	Maternal Participants: Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2339 / 3687 (63.44%)		
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	114 / 3687 (3.09%)		
occurrences (all)	116		
Congenital, familial and genetic			

disorders			
Tethered oral tissue			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences (all)	0		
Congenital naevus			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache (HEADACHE)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[1]	1009 / 3651 (27.64%)		
occurrences (all)	99999		
Pregnancy, puerperium and perinatal conditions			
Premature delivery			
subjects affected / exposed	153 / 3687 (4.15%)		
occurrences (all)	153		
Premature baby			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences (all)	0		
Low birth weight baby			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences (all)	0		
Jaundice neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Swelling (SWELLING)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[2]	8 / 3651 (0.22%)		
occurrences (all)	99999		
Injection site pain (PAIN AT INJECTION SITE)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			

subjects affected / exposed[3]	371 / 3651 (10.16%)		
occurrences (all)	99999		
Fatigue (FATIGUE)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[4]	1599 / 3651 (43.80%)		
occurrences (all)	99999		
Pyrexia (FEVER)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[5]	107 / 3651 (2.93%)		
occurrences (all)	99999		
Gastrointestinal disorders			
Vomiting (VOMITING)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[6]	254 / 3651 (6.96%)		
occurrences (all)	99999		
Nausea (NAUSEA)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[7]	705 / 3651 (19.31%)		
occurrences (all)	99999		
Diarrhoea (DIARRHEA)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[8]	416 / 3651 (11.39%)		
occurrences (all)	99999		
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			

Erythema (REDNESS)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[9]	8 / 3651 (0.22%)		
occurrences (all)	99999		
Dermatitis diaper			
subjects affected / exposed	0 / 3687 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Myalgia (MUSCLE PAIN)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[10]	626 / 3651 (17.15%)		
occurrences (all)	99999		
Arthralgia (JOINT PAIN)	Additional description: "99999" represents 'all occurrences' field data which is not applicable for reactogenicity events. Number of participants exposed: number of participants at risk for reactogenicity event and is different from the total safety population.		
alternative assessment type: Systematic			
subjects affected / exposed[11]	384 / 3651 (10.52%)		
occurrences (all)	99999		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.
[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.
[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.
[7] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.

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

Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.

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

Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.

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

Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.

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

Justification: Number of participants exposed is the number of participants at risk for this reactogenicity event and is different from the total safety population for this reporting group.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 March 2020	Protocol Amendment 1: The study title updated to reflect the revised study design and the final dose and formulation of RSVpreF selected for maternal participants in this study (120mcg) based on recent results from the C3671003 maternal phase 2b trial; alignment of study procedures for maternal participants prior to vaccination; the sentence regarding intrapartum antibiotic prophylaxis (IAP) details for maternal participants with a group B streptococcal (GBS) status refined. Further clarification provided regarding the collection and safety reporting requirements for medically attended respiratory tract illness (MA-RTI) associated with maternal and infant participants. Schedule of Activities for Infant Subjects: Visit flexibility was increased to prioritize subject safety and adherence to local guidance in the event of a COVID-19 outbreak or other outbreaks. The protocol safety reporting criteria and period for AEs, SAEs, and NDCMCs were streamlined. The protocol's safety, device deficiencies and endpoint reporting requirements were revised to ensure consistency with Pfizer's updated safety reporting requirements for Pfizer studies. Clarification text was added to support the safety and pregnancy reporting requirements for subjects who may experience exposure during pregnancy while in the study.
26 August 2020	Protocol Amendment 3: Exploratory endpoint objective refined - the planned statistical analysis period of "after 6 months of age" to "all-cause MA-RTIs and hospitalizations due to RSV. Incorporated revisions to align endpoints with study duration, and incorporated analysis plans for the healthcare utilization endpoints. Clarified RSV seasonality, enrolment across gestational ages with regards to eligibility and RSV surveillance periods during the study. Clarifications to the eligibility criteria, and refined the Tdap vaccine administration requirements text to describe the timing of vaccinations based on recent data from the C3671004 study. Due to COVID and other potential pandemic situations, some revisions were made to the conduct of the study including safety-related updates for study participants and investigational sites; Additional procedures were outlined for the investigational sites to increase efficiency and completeness in capturing study endpoints during the RSV surveillance periods. The benefit-risk text was updated to include Phase 2 safety data. Several Pfizer text revisions were incorporated regarding the safety reporting requirements for this study; the "SAE Reporting to Pfizer Safety via an Electronic Data Collection Tool" section was removed.
22 March 2021	Protocol Amendment 4: Increased study participant enrolment and included adolescent participants in the study. Statistical methods were updated and refined for both secondary and exploratory endpoints. Clarifications to the eligibility criteria including the gestational age determination, consent process for minors and foetal anomaly ultrasounds. Due to the COVID pandemic situations, additional revisions were made to the conduct of the study including, safety-related updates for maternal and infant participants pertaining to a positive test result for SARS-CoV-2 during the study, the use of licensed COVID-19 vaccines recommended during pregnancy, and acceptable standard of care assessments during study visits. Additional procedures were outlined for the investigational sites to increase efficiency and completeness in capturing study endpoints during COVID restrictive measures including nasal swab collection requirements from infant subjects during a confirmed MA-RTI episode. This was to provide flexibility and prioritize subject and site safety during the study.
12 January 2022	Protocol Amendment 5: Statistical update to the third secondary efficacy endpoint due to a typographical error. The administration requirements for maternal participants refined for licensed pertussis containing vaccines, licensed COVID-19 vaccines and COVID-19 vaccines authorized for temporary or emergency use.

01 June 2022	Protocol Amendment 6: Eligibility requirements pertaining to COVID concomitant vaccination requirements for study participants updated, revised the procedural assessment windows during the ongoing pandemic, and several Pfizer protocol template text revisions were incorporated pertaining to the dissemination of clinical study data. Statistical plans updated and refined in line with revised enrolment strategy and endpoint case -accrual plan based on RSV seasonality monitoring activities.
08 August 2022	Protocol Amendment 7: Based on regulatory feedback associated with protocol amendment 5, the statistical analysis was refined.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Infant participants were not vaccinated and therefore not exposed, no reactogenicity events. Database does not accept "0". Due to this limitation, exposed numbers are reported as total safety population for each infant group, which is not factual.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/37018474