Clinical trial results:
A Phase III, randomized, double-blind, placebo controlled multi-country study to demonstrate efficacy of a single dose of unadjuvanted RSV Maternal vaccine, administered IM to pregnant women 18 to 49 years of age, for prevention of RSV associated LRTI in their infants up to 6 months of age

Summary

EudraCT number	2020-001355-40
Trial protocol	FI FR BE IT ES
Global end of trial date	14 June 2023

Results information

Result version number	v2 (current)
This version publication date	19 October 2024
First version publication date	05 July 2024
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	212171

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04605159
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	20 October 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 June 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

- To assess the efficacy of a single dose of the RSV Maternal vaccine administered to maternal participants in preventing medically assessed, RSV-associated severe LRTIs in their infant participants up to 6 months of age.
- To assess the efficacy of a single dose of the RSV Maternal vaccine administered to maternal participants in preventing medically assessed, RSV-associated LRTIs of any severity in their infant participants up to 6 months of age.
- To evaluate the safety of the RSV Maternal vaccine in infants born to mothers who were vaccinated with a single intramuscular (IM) dose of study vaccine, up to 12 months after birth.

Protection of trial subjects:

All maternal participants were observed closely for at least 30 minutes after the administration of the vaccine/product. Appropriate medical treatment was readily available during the observation period in case of anaphylaxis and/or syncope. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible participants that had no contraindications to any components of the vaccines/products.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 November 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 566
Country: Number of subjects enrolled	Australia: 83
Country: Number of subjects enrolled	Bangladesh: 642
Country: Number of subjects enrolled	Belgium: 118
Country: Number of subjects enrolled	Brazil: 155
Country: Number of subjects enrolled	Canada: 92
Country: Number of subjects enrolled	Colombia: 541
Country: Number of subjects enrolled	Dominican Republic: 59
Country: Number of subjects enrolled	Finland: 389
Country: Number of subjects enrolled	France: 68
Country: Number of subjects enrolled	Honduras: 60
Country: Number of subjects enrolled	India: 119
Country: Number of subjects enrolled	Italy: 128
Country: Number of subjects enrolled	Korea, Republic of: 28

Country: Number of subjects enrolled	Mexico: 88
Country: Number of subjects enrolled	New Zealand: 434
Country: Number of subjects enrolled	Panama: 1471
Country: Number of subjects enrolled	Philippines: 695
Country: Number of subjects enrolled	South Africa: 1307
Country: Number of subjects enrolled	Spain: 1526
Country: Number of subjects enrolled	Taiwan: 229
Country: Number of subjects enrolled	Thailand: 114
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	United States: 2280
Worldwide total number of subjects	11194
EEA total number of subjects	2229

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	323
Newborns (0-27 days)	4912
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	5959
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 11194 participants (5959 maternal participants and 5235 infants) completed the informed consent process, of which 5328 maternal participants were exposed to the study intervention, and 5235 infants were born to those exposed mothers (RSV MAT Group - Mother and Placebo Group - Mother). Therefore, 10563 participants started the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

The study was conducted in a double-blinded manner, but the study was unblinded following the decision to stop enrollment and vaccination in the study due to a safety signal.

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV MAT Group - Mother

Arm description:

Maternal participants received a single dose of the RSV MAT vaccine administered at Day 1 in this study.

Arm type	Experimental
Investigational medicinal product name	RSV MAT
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose of the RSV MAT vaccine reconstituted with NaCl solution, administered intramuscularly in the non-dominant arm, at Day 1.

Arm title	Placebo Group - Mother

Arm description:

Maternal participants received a single dose of placebo administered at Day 1 in this study.

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

Dosage and administration details:

Single dose of Placebo (lyophilized sucrose reconstituted with NaCl solution), administered intramuscularly in the non-dominant arm, at Day 1.

Arm title	RSV MAT Group - Infant

Arm description:

This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Placebo Group - Infant

Arm description:

This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1[1]	RSV MAT Group - Mother	Placebo Group - Mother	RSV MAT Group - Infant
Started	3557	1771	3494
Completed	3374	1657	3236
Not completed	183	114	258
Consent withdrawn by subject	66	37	68
Adverse event, non-fatal	6	3	21
Migrated / moved from the study area	32	22	41
Unspecified	1	2	7
Lost to follow-up	74	45	119
Protocol deviation	4	5	2

Number of subjects in period 1[1]	Placebo Group - Infant
Started	1741
Completed	1583
Not completed	158
Consent withdrawn by subject	50
Adverse event, non-fatal	4
Migrated / moved from the study area	21
Unspecified	3
Lost to follow-up	80
Protocol deviation	-

Notes:

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

Justification: A total of 11194 participants (5959 maternal participants and 5235 infants) completed the informed consent process, of which 5328 maternal participants were exposed to the study intervention, and 5235 infants were born to those exposed mothers (RSV MAT Group - Mother and Placebo Group - Mother). Therefore, 10563 participants started the study.

Baseline characteristics

Reporting groups	
Reporting group title	RSV MAT Group - Mother
Reporting group description:	
Maternal participants received a single dose of the RSV MAT vaccine administered at Day 1 in this study.	
Reporting group title	Placebo Group - Mother
Reporting group description:	
Maternal participants received a single dose of placebo administered at Day 1 in this study.	
Reporting group title	RSV MAT Group - Infant
Reporting group description:	
This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy.	
Reporting group title	Placebo Group - Infant
Reporting group description:	
This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy.	

Reporting group values	RSV MAT Group - Mother	Placebo Group - Mother	RSV MAT Group - Infant
Number of subjects	3557	1771	3494
Age Categorical Units: Participants			
0 to 1 years of age	0	0	3494
18 to 34 years of age	2866	1408	0
35 to 39 years of age	581	300	0
40 to 49 years of age	110	63	0
Sex/Gender, Customized Units: Participants			
Female	3557	1771	1739
Male	0	0	1753
Other, Unspecified	0	0	2
Race/Ethnicity, Customized Units: Subjects			
ASIAN	663	326	641
BLACK OR AFRICAN AMERICAN	517	251	463
WHITE	1669	838	1634
OTHER, UNSPECIFIED	685	345	730
OTHER, DEIDENTIFIED	23	11	26

Reporting group values	Placebo Group - Infant	Total	
Number of subjects	1741	10563	
Age Categorical Units: Participants			
0 to 1 years of age	1741	5235	
18 to 34 years of age	0	4274	
35 to 39 years of age	0	881	
40 to 49 years of age	0	173	

Sex/Gender, Customized Units: Participants			
Female	867	7934	
Male	873	2626	
Other, Unspecified	1	3	
Race/Ethnicity, Customized Units: Subjects			
ASIAN	321	1951	
BLACK OR AFRICAN AMERICAN	234	1465	
WHITE	816	4957	
OTHER, UNSPECIFIED	348	2108	
OTHER, DEIDENTIFIED	22	82	

End points

End points reporting groups

Reporting group title	RSV MAT Group - Mother

Reporting group description:

Maternal participants received a single dose of the RSV MAT vaccine administered at Day 1 in this study.

Reporting group title	Placebo Group - Mother

Reporting group description:

Maternal participants received a single dose of placebo administered at Day 1 in this study.

Reporting group title	RSV MAT Group - Infant

Reporting group description:

This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy.

Reporting group title	Placebo Group - Infant

Reporting group description:

This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy.

Subject analysis set title	RSV MAT Group
Subject analysis set type	Per protocol

Subject analysis set description:

This group consisted of pairs of maternal participants from RSV MAT Group - Mother and infant participants from RSV MAT Group - Infant.

Subject analysis set title	Placebo Group
Subject analysis set type	Per protocol

Subject analysis set description:

This group consisted of pairs of maternal participants from Placebo Group - Mother and infant participants from Placebo Group - Infant.

Primary: Number of infant participants with medically assessed, RSV-associated lower respiratory tract illnesses (LRTIs) of any severity and RSV-associated severe LRTIs from birth to Day 181 post-birth

End point title	Number of infant participants with medically assessed, RSV-associated lower respiratory tract illnesses (LRTIs) of any severity and RSV-associated severe LRTIs from birth to Day 181 post-birth[1][2]

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND a blood oxygen saturation by pulse oximetry (SpO2) lower than (<) 95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by a SpO2 <93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Primary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants				
RSV-associated LRTIs of any severity	16	24		
RSV-associated severe LRTIs	8	14		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one serious adverse event (SAE) from birth to Day 181 post-birth

End point title	Number of infant participants with at least one serious adverse event (SAE) from birth to Day 181 post-birth[3][4]

End point description:

An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect or resulted in other situations that were considered serious per medical or scientific judgment. At least one SAE = occurrence of at least one SAE regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/legally acceptable representative(s) (LARs) completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[3] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494	1741		
Units: Participants	640	323		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one adverse event (AE) leading to study withdrawal from birth to Day 181 post-birth

End point title	Number of infant participants with at least one adverse event (AE) leading to study withdrawal from birth to Day 181 post-birth[5][6]

End point description:

A participant was considered a 'withdrawal' from the study when no study procedure has occurred, no follow-up has been performed and no further information has been collected for this participant from the date of withdrawal/last contact. Participants who were withdrawn from the study because of AEs were clearly distinguished from participants who were withdrawn for other reasons. Investigators followed participants who were withdrawn from the study as a result of an AE until the event was resolved. At least one AE leading to study withdrawal = occurrence of at least one AE leading to study withdrawal regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/legally acceptable representative(s) (LARs) completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[5] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[6] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494	1741		
Units: Participants	19	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one medically attended AE (MAE) from birth to Day 181 post-birth

End point title	Number of infant participants with at least one medically attended AE (MAE) from birth to Day 181 post-birth[7][8]

End point description:

An MAE is defined as an unsolicited AE, such as a symptom or illness, which required hospitalization, or emergency room visit, or visit to/by a health care provider. At least one MAE = occurrence of at least one MAE regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/legally acceptable representative(s) (LARs) completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[7] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494	1741		
Units: Participants	2321	1135		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one SAE from birth to Day 366 post-birth

End point title	Number of infant participants with at least one SAE from birth to Day 366 post-birth[9][10]

End point description:

An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect or resulted in other situations that were considered serious per medical or scientific judgment. At least one SAE = occurrence of at least one SAE regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth to Day 366 post-birth

Notes:

[9] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[10] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494	1741		
Units: Participants	731	371		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one AE leading to study withdrawal from birth to Day 366 post-birth

End point title	Number of infant participants with at least one AE leading to study withdrawal from birth to Day 366 post-birth[11][12]

End point description:

A participant was considered a 'withdrawal' from the study when no study procedure has occurred, no

follow-up has been performed and no further information has been collected for this participant from the date of withdrawal/last contact. Participants who were withdrawn from the study because of AEs were clearly distinguished from participants who were withdrawn for other reasons. Investigators followed participants who were withdrawn from the study as a result of an AE until the event was resolved. At least one AE leading to study withdrawal = occurrence of at least one AE leading to study withdrawal regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth to Day 366 post-birth

Notes:

[11] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[12] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494	1741		
Units: Participants	21	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of infant participants with at least one MAE from birth to Day 366 post-birth

End point title	Number of infant participants with at least one MAE from birth to Day 366 post-birth[13][14]

End point description:

An MAE is defined as an unsolicited AE, such as a symptom or illness, which required hospitalization, or emergency room visit, or visit to/by a health care provider. At least one MAE = occurrence of at least one MAE regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for infants, which included the infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Primary

End point timeframe:

From birth to Day 366 post-birth

Notes:

[13] - 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: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[14] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494	1741		
Units: Participants	2706	1330		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with RSV-associated hospitalizations from birth to Day 181 post-birth

End point title	Number of infant participants with RSV-associated hospitalizations from birth to Day 181 post-birth[15]

End point description:

RSV-associated hospitalization is defined as a confirmed RSV infection and hospitalized for acute medical condition. Hospitalization is defined as admission for observation or treatment based on the judgment of a health care provider.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	14	14		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 366 post-birth

End point title	Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 366 post-birth[16]

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO2 <95%, OR respiratory rate increase AND a confirmed RSV infection. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 366 post-birth

Notes:

[16] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	67	43		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated severe LRTIs for RSV subtype A and RSV subtype B separately from birth to Day 181 post-birth

End point title	Number of infant participants with medically assessed, RSV-associated severe LRTIs for RSV subtype A and RSV subtype B separately from birth to Day 181 post-birth[17]

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO2 <95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by an SpO2 <93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI. The RSV subtypes assessed for this analysis were RSV subtype A and RSV subtype B.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants which included all the infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants				
RSV A	2	3		
RSV B	6	11		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 366 post-birth

End point title	Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 366 post-birth[18]

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO2 <95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by an SpO2 <93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 366 post-birth

Notes:

[18] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	38	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with all-cause LRTIs with hospitalization from birth to Day 181 post-birth

End point title	Number of infant participants with all-cause LRTIs with hospitalization from birth to Day 181 post-birth[19]

End point description:

All-cause LRTI was characterized by history of cough OR difficulty in breathing, AND SpO2 < 95%, OR respiratory rate increase. Hospitalization is defined as admission for observation or treatment based on the judgment of a health care provider.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	30	22		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with all-cause LRTIs from birth to Day 181 post-birth

End point title	Number of infant participants with all-cause LRTIs from birth to Day 181 post-birth[20]

End point description:

All-cause LRTI was characterized by history of cough OR difficulty in breathing, AND SpO2 < 95%, OR respiratory rate increase.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all the infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[20] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	162	103		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated LRTIs of any severity for RSV subtype A and RSV subtype B separately from birth to Day 181 post-birth

End point title	Number of infant participants with medically assessed, RSV-associated LRTIs of any severity for RSV subtype A and RSV subtype B separately from birth to Day 181 post-birth[21]

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO2 <95%, OR respiratory rate increase AND a confirmed RSV infection. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI. The RSV subtypes assessed for this analysis were RSV subtype A and RSV subtype B.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal

participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants				
RSV A	6	8		
RSV B	10	16		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 121 post-birth

End point title	Number of infant participants with medically assessed, RSV-associated severe LRTIs from birth to Day 121 post-birth[22]

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO2 <95%, OR respiratory rate increase AND a confirmed RSV infection. An RSV-associated severe LRTI met the case definition of RSV-LRTI AND was additionally characterized by an SpO2 <93%, OR lower chest wall in-drawing, OR inability to feed, OR failure to respond/unconscious. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 121 post-birth

Notes:

[22] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	6	9		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for maternal participants at Day 1, at Day 31 and at delivery

End point title	RSV-A neutralizing antibody titers for maternal participants at Day 1, at Day 31 and at delivery[23]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as geometric mean titers (GMTs).
The analysis was performed on the Per Protocol - Immunogenicity set for maternal participants, which included all maternal participants who received the study intervention to which they were randomized and had post-vaccination immunogenicity data available for the specified analysis at each of the specified time points (i.e. Day 1, Day 31, delivery) minus those participants with protocol deviations that led to exclusion.

End point type	Secondary

End point timeframe:

At Day 1 (before study intervention administration), at Day 31 and at delivery

Notes:

[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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	404	196		
Units: Titers				
geometric mean (confidence interval 95%)				
Day 1 (N=404;196)	637.2 (589.4 to 688.8)	594.9 (527.3 to 671.2)		
Day 31 (N=317;148)	9196.9 (8310.8 to 10177.6)	673.5 (578.8 to 783.7)		
Delivery (N=404;178)	5703.1 (5196.3 to 6259.3)	657.7 (575.4 to 751.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with all-cause pneumonia from birth to Day 181 post-birth

End point title	Number of infant participants with all-cause pneumonia from birth to Day 181 post-birth[24]

End point description:

The number of infant participants with all-cause pneumonia is presented in this outcome measure.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 181 post-birth

Notes:

[24] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	36	17		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with RSV-associated medically attended RTIs (RSV-MA-RTIs) from study intervention administration (Day 1) to Day 181 post-delivery

End point title	Number of maternal participants with RSV-associated medically attended RTIs (RSV-MA-RTIs) from study intervention administration (Day 1) to Day 181 post-delivery[25]

End point description:

RSV-associated MA-RTI is defined as a medically attended visit for RTI symptoms and confirmed RSV infection.
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From study intervention administration (Day 1) to Day 181 post-delivery

Notes:

[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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants	3	6		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with RSV-associated hospitalizations from birth to Day 366 post-birth

End point title	Number of infant participants with RSV-associated

	hospitalizations from birth to Day 366 post-birth[26]

End point description:

RSV-associated hospitalization is defined as a confirmed RSV infection and hospitalized for acute medical condition. Hospitalization is defined as admission for observation or treatment based on the judgment of a health care provider.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 366 post-birth

Notes:

[26] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	41	26		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 121 post-birth

End point title	Number of infant participants with medically assessed, RSV-associated LRTIs of any severity from birth to Day 121 post-birth[27]

End point description:

An RSV-associated LRTI of any severity was characterized by a history of cough OR difficulty in breathing, AND an SpO2 <95%, OR respiratory rate increase AND a confirmed RSV infection. Medically assessed = the infant was evaluated by a healthcare professional for the LRTI.
The analysis was performed on the Modified Full Analysis - Efficacy set for infants, which included all infant participants in the Exposed Set who were born after at least 4 weeks of their maternal participants vaccination.

End point type	Secondary

End point timeframe:

From birth to Day 121 post-birth

Notes:

[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3426	1711		
Units: Participants	9	15		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at delivery or within 72 hours after birth

End point title	RSV-A neutralizing antibody titers for infant participants at delivery or within 72 hours after birth[28]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs. The titers were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 72 hours after birth (if no cord blood sample could be obtained).
The analysis was performed on the Per Protocol - Immunogenicity set for infants, which included all infant participants in the Exposed set who had post-delivery/birth immunogenicity data available for the specified analysis at the specified time points (i.e. at delivery or within 72 hours after birth), minus those who (a) were born less than 4 weeks post- maternal participant vaccination and/ or (b) had protocol deviations that led to exclusion.

End point type	Secondary

End point timeframe:

At delivery or within 72 hours after birth

Notes:

[28] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	197	82		
Units: Titers				
geometric mean (confidence interval 95%)	9466.2 (8398.6 to 10669.5)	725.9 (593.1 to 888.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at Day 43 post-birth

End point title	RSV-A neutralizing antibody titers for infant participants at Day 43 post-birth[29]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs.
The analysis was performed on a sub-cohort from the Per Protocol - Immunogenicity set for infants, which included the infant participants for whom blood samples were collected for the specified analysis at Day 43 post-birth.

End point type	Secondary

End point timeframe:

At Day 43 post-birth

Notes:

[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	140	67		
Units: Titers				
geometric mean (confidence interval 95%)	4042.1 (3530.3 to 4628.2)	311.3 (250.3 to 387.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at Day 121 post-birth

End point title	RSV-A neutralizing antibody titers for infant participants at Day 121 post-birth[30]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs.
The analysis was performed on a sub-cohort from the Per Protocol - Immunogenicity set for infants, which included the infant participants for whom blood samples were collected for the specified analysis at Day 121 post-birth.

End point type	Secondary

End point timeframe:

At Day 121 post-birth

Notes:

[30] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	23		
Units: Titers				
geometric mean (confidence interval 95%)	682.4 (520.2 to 895.3)	74.8 (46.5 to 120.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for infant participants at Day 181 post-birth

End point title	RSV-A neutralizing antibody titers for infant participants at Day 181 post-birth[31]

End point description:

RSV-A neutralizing titers were determined by neutralization assay and expressed as GMTs.
The analysis was performed on a sub-cohort from the Per Protocol - Immunogenicity set for infants, which included the infant participants for whom blood samples were collected for the specified analysis at Day 181 post-birth.

End point type	Secondary

End point timeframe:

At Day 181 post-birth

Notes:

[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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44	9		
Units: Titers				
geometric mean (confidence interval 95%)	506.0 (432.4 to 592.3)	133.7 (52.4 to 341.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT immunoglobulin G (IgG)-specific antibody concentrations for maternal participants at delivery

End point title	RSV MAT immunoglobulin G (IgG)-specific antibody concentrations for maternal participants at delivery[32]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by enzyme-linked immunosorbent assay (ELISA) and expressed as geometric mean concentrations (GMCs) in ELISA units per milliliter (ELU/mL).
The analysis was performed on the Per Protocol - Immunogenicity set for maternal participants, which included all maternal participants who received the study intervention to which they were randomized and had post-vaccination immunogenicity data available for the specified analysis at the specified time point (i.e. delivery) minus those participants with protocol deviations that led to exclusion.

End point type	Secondary

End point timeframe:

At delivery

Notes:

[32] - 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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	405	178		
Units: ELU/mL				
geometric mean (confidence interval 95%)	62880 (58517 to 67568)	5600 (4949 to 6338)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with any solicited administration site events from Day 1 to Day 7 included

End point title	Number of maternal participants with any solicited administration site events from Day 1 to Day 7 included[33]

End point description:

Assessed solicited administration site events included erythema, pain and swelling at the injection site. Any pain = occurrence of the symptom regardless of intensity grade. Any erythema and swelling = symptom reported with a surface diameter greater than or equal to 20 millimeters.
The analysis was performed on the Solicited Safety set for maternal participants, which included all maternal participants who received the study intervention and who had solicited safety data available during the specified period (i.e. from Day 1 to Day 7 included).

End point type	Secondary

End point timeframe:

From Day 1 to Day 7 included

Notes:

[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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3090	1547		
Units: Participants				
Any Erythema	133	8		
Any Pain	1294	230		
Any Swelling	96	8		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG-specific antibody concentrations for infant participants at delivery or within 72 hours after birth

End point title	RSV MAT IgG-specific antibody concentrations for infant participants at delivery or within 72 hours after birth[34]

End point description:

RSV MAT IgG-specific antibody concentrations were determined by ELISA and expressed as GMCs in

ELU/mL. The antibody concentrations were measured on the cord blood sample collected at delivery, or on a blood sample collected from the infant within 72 hours after birth (only if no cord blood sample could be obtained at delivery).
The analysis was performed on the Per Protocol -Immunogenicity set for infants, which included all infant participants in the Exposed set who had post-delivery/birth immunogenicity data available for the specified analysis at the specified time points (i.e. at delivery or within 72 hours after birth), minus those who (a) were born less than 4 weeks post-maternal participant vaccination and/ or (b) had protocol deviations that led to exclusion.

End point type	Secondary

End point timeframe:

At delivery or within 72 hours after birth (only if no cord blood sample could be obtained at delivery)

Notes:

[34] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	230	97		
Units: ELU/mL				
geometric mean (confidence interval 95%)	94365 (86569 to 102864)	6610 (5688 to 7682)		

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric mean ratio (GMR) between cord blood and maternal RSV MAT immunoglobulin G (IgG)-specific antibody concentrations

End point title	Geometric mean ratio (GMR) between cord blood and maternal RSV MAT immunoglobulin G (IgG)-specific antibody concentrations

End point description:

The placental transfer ratio of RSV-MAT IgG-specific antibody concentration was determined from cord blood over that of the blood sample from mother at delivery. If no cord blood could be obtained, an infant blood sample was collected 72 hours after birth.
The analysis was performed on all pairs of maternal participants (from Per Protocol - Immunogenicity set for maternal participants) and their infants (from Per Protocol -Immunogenicity set for infants) with available results for this outcome measure at the specified time points.

End point type	Secondary

End point timeframe:

At delivery (for maternal participants) or within 72 hours after birth (for infant participants, only if no cord blood could be obtained)

End point values	RSV MAT Group	Placebo Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	150	60		
Units: Ratio				
geometric mean (confidence interval 95%)	1.46 (1.35 to 1.58)	1.39 (1.22 to 1.59)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with any solicited systemic events from Day 1 to Day 7 included

End point title	Number of maternal participants with any solicited systemic events from Day 1 to Day 7 included[35]

End point description:

Assessed solicited systemic events included abdominal pain, diarrhea, fatigue, headache, nausea, fever [temperature equal to or above (>=) 38 degrees Celsius (°C)/100.4 degrees Fahrenheit (°F), regardless of the location of measurement] and vomiting. Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination.
The analysis was performed on the Solicited Safety set for maternal participants, which included all maternal participants who received the study intervention and who had solicited safety data available during the specified period (i.e. from Day 1 to Day 7 included).

End point type	Secondary

End point timeframe:

From Day 1 to Day 7 included

Notes:

[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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3090	1547		
Units: Participants				
Any Abdominal pain	492	231		
Any Diarrhea	351	180		
Any Fatigue	1091	479		
Any Headache	942	442		
Any Nausea	599	306		
Any Fever	26	7		
Any Vomiting	276	149		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one SAE from Day 1 to Day 181 post-delivery

End point title	Number of maternal participants with at least one SAE from Day 1 to Day 181 post-delivery[36]

End point description:

An SAE is defined as any untoward medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of existing hospitalization, resulted in disability/incapacity, was a congenital anomaly/birth defect in the offspring of a study participant or resulted in abnormal pregnancy outcomes or in other situations that were considered serious per medical or scientific judgment. At least one SAE = occurrence of at least one SAE regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

[36] - 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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants	827	395		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one AE leading to study withdrawal from Day 1 to Day 181 post-delivery

End point title	Number of maternal participants with at least one AE leading to study withdrawal from Day 1 to Day 181 post-delivery[37]

End point description:

A participant was considered a 'withdrawal' from the study when no study procedure has occurred, no follow-up has been performed and no further information has been collected for this participant from the date of withdrawal/last contact. Participants who were withdrawn from the study because of AEs were clearly distinguished from participants who were withdrawn for other reasons. Investigators followed participants who were withdrawn from the study as a result of an AE until the event was resolved. At least one AE leading to study withdrawal = occurrence of at least one AE leading to study withdrawal regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 to Day 181 post-delivery

Notes:

[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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants	6	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with any unsolicited AEs from Day 1 to Day 30 included

End point title	Number of maternal participants with any unsolicited AEs from Day 1 to Day 30 included[38]

End point description:

An unsolicited AE is defined as any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms was reported as an unsolicited AE. Any = occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 to Day 30 included

Notes:

[38] - 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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants	629	297		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one MAE from Day 1 to Day 42 post-delivery

End point title	Number of maternal participants with at least one MAE from Day 1 to Day 42 post-delivery[39]

End point description:

An MAE is defined as an unsolicited AE, such as a symptom or illness, which required hospitalization, or emergency room visit, or visit to/by a health care provider. At least one MAE = occurrence of at least one MAE regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 to Day 42 post-delivery, an average of 2 months

Notes:

[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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants	1717	785		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with pregnancy outcomes from Day 1 to Day 42 post-delivery

End point title	Number of maternal participants with pregnancy outcomes from Day 1 to Day 42 post-delivery[40]

End point description:

Assessed pregnancy outcomes included live birth (LB) with no congenital anomalies, live birth (LB) with minor congenital anomaly(ies), live birth (LB) with at least 1 major congenital anomaly, fetal death (FD)/still birth (SB) with no congenital anomalies, fetal death (FD)/still birth (SB) with at least 1 major congenital anomaly and unknown outcome (includes participants withdrawn before/at delivery with no available data of pregnancy outcomes).
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 to Day 42 post-delivery, an average of 2 months

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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants				
LB with no congenital anomalies	3118	1555		
LB with only minor congenital anomaly(ies)	317	143		
LB with at least 1 major congenital anomaly	61	43		
FD/SB with no congenital anomalies	9	6		
FD/SB with at least 1 major congenital anomaly	2	0		
Unknown outcome	50	24		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with at least one all-cause MA-RTI from Day 1 to Day 181 post-delivery

End point title	Number of maternal participants with at least one all-cause MA-RTI from Day 1 to Day 181 post-delivery[41]

End point description:

All-cause MA-RTI occurred when the maternal participant visited a healthcare professional (e.g., a General Practitioner) for any respiratory symptom, including (but not limited to) cough, sore throat, sputum production and difficulty breathing. At least one all-cause MA-RTI = occurrence of at least one all-cause MA-RTI regardless of intensity grade or relation to vaccination.
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 to Day 181 post-delivery

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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants	317	144		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of maternal participants with pregnancy-related adverse events of special interest (AESIs) from Day 1 to Day 42 post-delivery

End point title	Number of maternal participants with pregnancy-related adverse events of special interest (AESIs) from Day 1 to Day 42 post-delivery[42]

End point description:

Pregnancy-related AESIs included chorioamnionitis, fetal growth restriction, gestational diabetes mellitus, gestational hypertension, pre-eclampsia, pre-eclampsia with severe features including eclampsia, maternal death, premature preterm rupture of membranes, preterm labor, provider-initiated preterm birth.
The analysis was performed on the Exposed Set for maternal participants, which included all maternal participants who received the study intervention.

End point type	Secondary

End point timeframe:

From Day 1 to Day 42 post-delivery, an average of 2 months

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 is only reporting values for the maternal participants.

End point values	RSV MAT Group - Mother	Placebo Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3557	1771		
Units: Participants				
Chorioamnionitis	30	14		
Fetal Growth Restriction	30	26		
Gestational Diabetes Mellitus	42	19		
Gestational Hypertension	85	41		
Pre-Eclampsia	74	36		
Pre-Eclampsia With Severe Features	58	28		
Maternal Death	2	1		
Premature Preterm Rupture Of Membranes	53	20		
Preterm Labor	141	57		
Provider-Initiated Preterm Birth	54	16		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of infant participants with neonatal AESIs from birth to Day 42 post-birth

End point title	Number of infant participants with neonatal AESIs from birth to Day 42 post-birth[43]

End point description:

Neonatal/infant AESIs included congenital anomalies (CAs) with functional defects, congenital anomalies (CAs) with internal structural defects, congenital anomalies (CAs) with major external structural defects, extremely low birth weight (<1000 grams), low birth weight (<2500 grams), very low birth weight (<1500 grams), neonatal death in a preterm live birth (gestational age >=28 and <37 weeks), neonatal death in a term live birth (>=37 weeks of gestational age), neonatal death in an extremely pre-term birth (gestational age >=22 and <28 weeks), preterm birth (<37 weeks of gestational age), small for gestational age.
The analysis was performed on the Exposed Set for infants, which included infants live-born to exposed maternal participants, whose parents/LARs completed the informed consent process and signed the informed consent form.

End point type	Secondary

End point timeframe:

From birth to Day 42 post-birth, an average of 2 months

Notes:

[43] - 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 is only reporting values for the infant participants.

End point values	RSV MAT Group - Infant	Placebo Group - Infant		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3494	1741		
Units: Participants				
CAs With Functional Defects	5	2		
CAs With Internal Structural Defects	23	16		
CAs With Major External Structural Defects	24	14		
Extremely Low Birth Weight (<1000 grams)	3	0		
Low Birth Weight (<2500 grams)	196	102		
Very Low Birth Weight (<1500 grams)	5	0		
Neonatal Death In A Preterm Live Birth	5	0		
Neonatal Death In A Term Live Birth	6	3		
Neonatal Death In An Extremely Pre-Term Birth	2	0		
Preterm Birth	237	86		
Small For Gestational Age	253	161		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Mothers: Solicited AEs: Day (D)1-D7&Unsolicited AEs:D1-D30 post-vaccination. AESIs&MAEs:D1-D42, deaths,(S)AEs leading to withdrawal,SAEs:D1-D181 post-delivery.
Infants: AESIs: birth-D42, deaths,SAEs,(S)AEs leading to withdrawal,MAEs:birth-D366 post-birth.

Adverse event reporting additional description:

All events presented in the SAEs & Non SAEs modules are reported for the Exposed set for maternal participants & Exposed set for infants during the specified timeframe.
The solicited events presented for the RSV MAT Group – Mother & Placebo Group – Mother in the End Points module are reported for the Solicited safety set for maternal participants.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	RSV MAT Group - Mother

Reporting group description:

Maternal participants randomized to the RSV MAT Group received a single dose of the RSV MAT vaccine administered, between 24 to 34 weeks of gestation at Day 1 in this study.

Reporting group title	Placebo Group - Infant

Reporting group description:

This group consisted of infants born to mothers (from Placebo Group - Mother) who received a single dose of placebo during pregnancy.

Reporting group title	RSV MAT Group - Infant

Reporting group description:

This group consisted of infants born to mothers (from RSV MAT Group - Mother) who received a single dose of RSV MAT vaccine during pregnancy.

Reporting group title	Placebo Group - Mother

Reporting group description:

Maternal participants randomized to the Placebo Group received a single dose of placebo administered, between 24 to 34 weeks of gestation, at Day 1 in this study.

Serious adverse events	RSV MAT Group - Mother	Placebo Group - Infant	RSV MAT Group - Infant
Total subjects affected by serious adverse events			
subjects affected / exposed	827 / 3557 (23.25%)	371 / 1741 (21.31%)	731 / 3494 (20.92%)
number of deaths (all causes)	2	4	20
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Granulosa cell tumour of the testis			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 haemangioma			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoproliferative disorder			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian epithelial cancer			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinoblastoma			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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			
Aortic stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Deep vein thrombosis			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Haemodynamic instability			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hypertensive crisis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
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	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Hypotension			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 hypotension			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Renovascular hypertension			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Shock			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Subgaleal haematoma			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 / 1
Venous thrombosis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	37 / 3557 (1.04%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	1 / 37	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abnormal labour			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Abortion spontaneous			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Amniorrhoea			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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	21 / 3557 (0.59%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 21	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breech presentation			
subjects affected / exposed	20 / 3557 (0.56%)	0 / 1741 (0.00%)	0 / 3494 (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

Caput succedaneum			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cephalhaematoma			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Cephalo-pelvic disproportion			
subjects affected / exposed	23 / 3557 (0.65%)	0 / 1741 (0.00%)	0 / 3494 (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
Cervix dystocia			
subjects affected / exposed	7 / 3557 (0.20%)	0 / 1741 (0.00%)	0 / 3494 (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
Eclampsia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Face presentation			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Failed induction of labour			
subjects affected / exposed	27 / 3557 (0.76%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 27	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed trial of labour			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
False labour			

subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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 damage			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (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 disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
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 distress syndrome			
subjects affected / exposed	125 / 3557 (3.51%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 125	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal dystocia			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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 macrosomia			
subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	0 / 3494 (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
Foetal hypokinesia			
subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	1 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal growth restriction			
subjects affected / exposed	17 / 3557 (0.48%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 17	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal malposition			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
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 malpresentation			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Gestational hypertension			
subjects affected / exposed	46 / 3557 (1.29%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 46	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational diabetes			
subjects affected / exposed	10 / 3557 (0.28%)	0 / 1741 (0.00%)	0 / 3494 (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
HELLP syndrome			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemorrhage in pregnancy			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (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
High foetal head			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
High risk infant			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hypoxic ischaemic encephalopathy neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Labour complication			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 / 3557 (0.00%)	51 / 1741 (2.93%)	89 / 3494 (2.55%)
occurrences causally related to treatment / all	0 / 0	0 / 51	0 / 91
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Large for dates baby			
subjects affected / exposed	1 / 3557 (0.03%)	3 / 1741 (0.17%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Low birth weight baby			
subjects affected / exposed	0 / 3557 (0.00%)	21 / 1741 (1.21%)	53 / 3494 (1.52%)
occurrences causally related to treatment / all	0 / 0	0 / 21	1 / 53
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 5
Maternal death			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Meconium in amniotic fluid			

subjects affected / exposed	15 / 3557 (0.42%)	0 / 1741 (0.00%)	0 / 3494 (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
Morning sickness			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Obstructed labour			
subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	0 / 3494 (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
Oligohydramnios			
subjects affected / exposed	19 / 3557 (0.53%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	1 / 19	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic haematoma obstetric			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Peripartum cardiomyopathy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placenta praevia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
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 polyp			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyhydramnios			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	105 / 3557 (2.95%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 106	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Postpartum haemorrhage			
subjects affected / exposed	46 / 3557 (1.29%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 47	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Precipitate labour			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 3557 (0.00%)	30 / 1741 (1.72%)	84 / 3494 (2.40%)
occurrences causally related to treatment / all	0 / 0	0 / 30	1 / 84
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 4
Premature labour			
subjects affected / exposed	56 / 3557 (1.57%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	2 / 56	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	11 / 3557 (0.31%)	0 / 1741 (0.00%)	0 / 3494 (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
Premature separation of placenta			

subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	0 / 3494 (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	66 / 3557 (1.86%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 66	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prolonged pregnancy			
subjects affected / exposed	8 / 3557 (0.22%)	0 / 1741 (0.00%)	0 / 3494 (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	11 / 3557 (0.31%)	0 / 1741 (0.00%)	0 / 3494 (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
Preterm premature rupture of membranes			
subjects affected / exposed	37 / 3557 (1.04%)	0 / 1741 (0.00%)	0 / 3494 (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
Retained placenta or membranes			
subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	0 / 3494 (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
Retained products of conception			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shoulder dystocia			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Stillbirth			

subjects affected / exposed	11 / 3557 (0.31%)	0 / 1741 (0.00%)	0 / 3494 (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
Small for dates baby			
subjects affected / exposed	0 / 3557 (0.00%)	15 / 1741 (0.86%)	21 / 3494 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 15	0 / 21
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Threatened labour			
subjects affected / exposed	28 / 3557 (0.79%)	0 / 1741 (0.00%)	0 / 3494 (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
Umbilical cord around neck			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Traumatic delivery			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transverse presentation			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Umbilical cord compression			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (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
Umbilical cord prolapse			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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 hypotonus			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 hypertonus			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 contractions during pregnancy			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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 atony			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Weight decrease neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Crying			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	13 / 3494 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 3	0 / 13
Developmental delay			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Dysplasia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Fatigue			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Feeling jittery			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised oedema			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothermia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (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
Inflammation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Macrosomia			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden infant death syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 death			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Anaphylactic reaction			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 type incompatibility			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	1 / 3494 (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
Milk allergy			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhesus incompatibility			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Reproductive system and breast disorders			
Abnormal uterine bleeding			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Cervical dysplasia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Enlarged clitoris			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital labial adhesions			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Pelvic haematoma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shortened cervix			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Vaginal haemorrhage			

subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Vaginal discharge			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory failure			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Apnoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 / 1
Atelectasis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Asthmatic crisis			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Brief resolved unexplained event			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Bronchial obstruction			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial hyperreactivity			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Choking			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Chronic respiratory disease			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cough			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cyanosis neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Dyspnoea			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Epistaxis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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	1 / 3557 (0.03%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile apnoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 aspiration syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	8 / 1741 (0.46%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Neonatal aspiration			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Neonatal dyspnoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal hypoxia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal asphyxia			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Neonatal pneumothorax			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 pulmonary hypertension			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 respiratory depression			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 respiratory distress			
subjects affected / exposed	0 / 3557 (0.00%)	31 / 1741 (1.78%)	66 / 3494 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 31	2 / 66
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neonatal respiratory distress syndrome			

subjects affected / exposed	0 / 3557 (0.00%)	7 / 1741 (0.40%)	23 / 3494 (0.66%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 23
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Neonatal tachypnoea			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pulmonary artery stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 embolism			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 vein stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 venous hypertension			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 hypertension			

subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Respiratory depression			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Respiratory arrest			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Respiratory depth decreased			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 disorder neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Stridor			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Tachypnoea			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 3557 (0.00%)	16 / 1741 (0.92%)	37 / 3494 (1.06%)
occurrences causally related to treatment / all	0 / 0	0 / 16	0 / 37
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Wheezing			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
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			
Biliary colic			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary dilatation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cholecystitis acute			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (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
Cholecystitis			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Cholelithiasis			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (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
Cholestasis of pregnancy			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (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
Cholestasis			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 rupture			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	14 / 1741 (0.80%)	26 / 3494 (0.74%)
occurrences causally related to treatment / all	0 / 0	0 / 14	0 / 26
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Apgar score low			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Blood pressure increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
C-reactive protein increased			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Foetal heart rate abnormal			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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 heart rate decreased			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Gynaecological examination abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Hepatitis B surface antigen positive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Male genital examination abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Medical observation			

subjects affected / exposed	1 / 3557 (0.03%)	3 / 1741 (0.17%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oxygen saturation decreased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Viral test positive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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, poisoning and procedural complications			
Abdominal injury			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 fracture			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachial plexus injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Clavicle fracture			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Contusion			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Exposure to SARS-CoV-2			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Extradural haematoma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Face injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Failed forceps delivery			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Fall			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	0 / 3494 (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
Foetal exposure during delivery			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture of clavicle due to birth trauma			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Fractured skull depressed			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Head injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Humerus fracture			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Multiple fractures			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Perineal injury			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull fracture			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haemorrhage			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Thermal burn			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (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
Traumatic haemorrhage			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
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	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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 cervical laceration			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			

subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Vulvovaginal injury			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haematoma			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Adrenogenital syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankyloglossia congenital			
subjects affected / exposed	0 / 3557 (0.00%)	7 / 1741 (0.40%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aplasia cutis congenita			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Anomalous pulmonary venous connection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Arteriovenous malformation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	10 / 1741 (0.57%)	22 / 3494 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 11	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Atrioventricular septal defect			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Bicuspid aortic valve			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biotinidase deficiency			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Branchial cyst			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Brachycephaly			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Buried penis syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
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 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Choanal atresia			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 lip and palate			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 lip			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coarctation of the aorta			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chordee			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 cerebral cyst			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital choroid plexus cyst			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 cystic kidney disease			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 inguinal hernia			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 ectopic bladder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 facial diplegia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 great vessel anomaly			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 hydronephrosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital diaphragmatic hernia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 knee dislocation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 laryngeal stridor			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 melanosis			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 of skull			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 syphilis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital nephrotic syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 pneumonia			
subjects affected / exposed	0 / 3557 (0.00%)	5 / 1741 (0.29%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Congenital pyelocaliectasis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital skin dimples			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 myasthenic syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 torticollis			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 toxoplasmosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 3557 (0.00%)	5 / 1741 (0.29%)	16 / 3494 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 16
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniosynostosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystic fibrosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cytogenetic abnormality			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	9 / 1741 (0.52%)	12 / 3494 (0.34%)
occurrences causally related to treatment / all	0 / 0	0 / 10	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dextrocardia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated neonatal herpes simplex			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Dysmorphism			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic kidney			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Erythroblastosis foetalis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Epispadias			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Fibromatosis colli of infancy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Genitalia external ambiguous			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Haemangioma congenital			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart disease congenital			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (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 / 1
Heterotaxia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hypospadias			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 6	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertelorism			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal malrotation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Kidney duplex			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Iris coloboma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Macrocephaly			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Macrostomia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Menkes' syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microtia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micropenis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Micrognathia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myotonic dystrophy			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Multiple congenital abnormalities			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (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
Oesophageal atresia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrodysplasia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Osteogenesis imperfecta			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Penoscrotal fusion			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Penile torsion			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Pectus excavatum			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patent ductus arteriosus			
subjects affected / exposed	0 / 3557 (0.00%)	8 / 1741 (0.46%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Polydactyly			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	5 / 3494 (0.14%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery stenosis congenital			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyloric stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Renal hypoplasia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Shone complex			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 hypoplasia			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syringomyelia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Thalassaemia alpha			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Talipes			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trisomy 21			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urachal abnormality			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Vascular malformation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 septal defect			

subjects affected / exposed	1 / 3557 (0.03%)	5 / 1741 (0.29%)	12 / 3494 (0.34%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 12
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac disorders			
Acute left ventricular failure			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Arrhythmia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Bradycardia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia foetal			
subjects affected / exposed	10 / 3557 (0.28%)	0 / 1741 (0.00%)	0 / 3494 (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
Bradycardia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiogenic shock			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 / 1
Cardiac failure			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 / 1
Cardiac arrest			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Foetal arrhythmia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 heart rate deceleration abnormality			
subjects affected / exposed	11 / 3557 (0.31%)	0 / 1741 (0.00%)	0 / 3494 (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
Left ventricular failure			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Left ventricular hypertrophy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Nonreassuring foetal heart rate pattern			
subjects affected / exposed	19 / 3557 (0.53%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 19	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary valve stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular hypertrophy			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 tachycardia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Supravalvular aortic stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (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
Ventricular dysfunction			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Nervous system disorders			
Brain hypoxia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cerebral cyst			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Cerebral ventricle dilatation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Extrapyramidal disorder			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 / 3557 (0.00%)	2 / 1741 (0.11%)	7 / 3494 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fontanelle bulging			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Headache			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Infant irritability			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	1 / 3557 (0.03%)	3 / 1741 (0.17%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile spasms			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Kernicterus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Intraventricular haemorrhage neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial aneurysm			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Lacunar stroke			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Myoclonus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Migraine			

subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Monoplegia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 seizure			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Poor sucking reflex			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Seizure			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Seizure like phenomena			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (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 / 1
Syncope			

subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Tethered cord syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Unresponsive to stimuli			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Blood and lymphatic system disorders			
Anaemia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Anaemia macrocytic			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Anaemia			
subjects affected / exposed	11 / 3557 (0.31%)	1 / 1741 (0.06%)	6 / 3494 (0.17%)
occurrences causally related to treatment / all	0 / 11	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Blood loss anaemia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Coagulopathy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Disseminated intravascular coagulation			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Foetal anaemia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hypersplenism			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Leukocytosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycythaemia			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Thrombocytopenia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (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
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Deafness bilateral			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Vertigo			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Eye disorders			
Retinopathy of prematurity			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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			
Abdominal pain lower			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (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

Abdominal pain			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Abdominal distension			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Abdominal pain upper			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 fistula			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Diarrhoea			
subjects affected / exposed	1 / 3557 (0.03%)	5 / 1741 (0.29%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food poisoning			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 pain			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Haematochezia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Haemorrhoids			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Intestinal obstruction			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infantile colic			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Necrotising enterocolitis neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Necrotising colitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nausea			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Obstructive pancreatitis			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Oesophageal stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Pancreatitis relapsing			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Pancreatitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Peptic ulcer			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 and subcutaneous tissue disorders			
Ecchymosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythema toxicum neonatorum			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Erythema multiforme			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Henoch-Schonlein purpura			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Melanoderma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Umbilical haemorrhage			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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	1 / 3557 (0.03%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bladder perforation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (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
Nephrolithiasis			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Pelvi-ureteric obstruction			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelocaliectasis			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	4 / 3494 (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
Renal disorder in pregnancy			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Urinary retention			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Goitre			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Retrognathia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Rheumatoid arthritis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Trigger finger			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Torticollis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Abscess neck			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Abscess			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Anal abscess			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 cavity infection			
subjects affected / exposed	12 / 3557 (0.34%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 12	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	4 / 3557 (0.11%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Breast abscess			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
COVID-19			
subjects affected / exposed	8 / 3557 (0.22%)	10 / 1741 (0.57%)	22 / 3494 (0.63%)
occurrences causally related to treatment / all	0 / 8	0 / 11	0 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			

subjects affected / exposed	4 / 3557 (0.11%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (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
Bronchiolitis			
subjects affected / exposed	0 / 3557 (0.00%)	24 / 1741 (1.38%)	56 / 3494 (1.60%)
occurrences causally related to treatment / all	0 / 0	0 / 25	0 / 61
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cellulitis orbital			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Cellulitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conjunctivitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Dacryocystitis			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dengue fever			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Device related infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Dysentery			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (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
Escherichia bacteraemia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 pyelonephritis			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Gastroenteritis			
subjects affected / exposed	3 / 3557 (0.08%)	7 / 1741 (0.40%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 3	0 / 7	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Gastroenteritis bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Gastroenteritis salmonella			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 viral			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Gastrointestinal infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Gastroenteritis norovirus			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital herpes			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin abscess			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Herpes simplex			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Impetigo			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (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
Influenza			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Intestinal sepsis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Laryngitis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Leishmaniasis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	5 / 3494 (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
Mastitis bacterial			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Mastitis			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (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
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 aseptic			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Mastoiditis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 viral			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus bronchiolitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metapneumovirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Myiasis			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 / 3557 (0.00%)	3 / 1741 (0.17%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal pneumonia			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	5 / 3494 (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 / 1
Norovirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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
Oral herpes			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Omphalitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Ophthalmia neonatorum			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Osteomyelitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Otitis externa			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Otitis media			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papilloma viral infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pertussis			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Pharyngotonsillitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Pneumonia			
subjects affected / exposed	4 / 3557 (0.11%)	21 / 1741 (1.21%)	46 / 3494 (1.32%)
occurrences causally related to treatment / all	0 / 4	0 / 22	0 / 53
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Pneumonia adenoviral			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia parainfluenzae viral			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Pneumonia pneumococcal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	9 / 3494 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural pneumonia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Postoperative wound infection			
subjects affected / exposed	7 / 3557 (0.20%)	0 / 1741 (0.00%)	0 / 3494 (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
Postpartum sepsis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Puerperal infection			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (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
Pyelonephritis			
subjects affected / exposed	4 / 3557 (0.11%)	3 / 1741 (0.17%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 4	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash pustular			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 syncytial virus bronchiolitis			
subjects affected / exposed	0 / 3557 (0.00%)	15 / 1741 (0.86%)	19 / 3494 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 15	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 tract infection			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (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
Respiratory syncytial virus infection			

subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Rotavirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Salmonella bacteraemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Rhinovirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (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 / 1
Sepsis neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	18 / 1741 (1.03%)	46 / 3494 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 19	0 / 46
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 4
Septic shock			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Staphylococcal sepsis			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Streptococcal sepsis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Systemic viral infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Syphilis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suspected COVID-19			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroglossal cyst infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Tonsillitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Umbilical sepsis			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 3557 (0.03%)	4 / 1741 (0.23%)	4 / 3494 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 4	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urachal sinus infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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 neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Urinary tract infection			
subjects affected / exposed	14 / 3557 (0.39%)	5 / 1741 (0.29%)	25 / 3494 (0.72%)
occurrences causally related to treatment / all	0 / 14	0 / 5	0 / 28
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral rash			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	4 / 3494 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (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
Wound sepsis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Carnitine deficiency			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	8 / 1741 (0.46%)	10 / 3494 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Feeding disorder			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (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
Food intolerance			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hyperglycaemia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (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
Hypomagnesaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hypokalaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	9 / 1741 (0.52%)	27 / 3494 (0.77%)
occurrences causally related to treatment / all	0 / 0	0 / 9	0 / 27
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 3557 (0.00%)	5 / 1741 (0.29%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Malnutrition			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
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 hypocalcaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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
Underweight			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (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

Serious adverse events	Placebo Group - Mother		
Total subjects affected by serious adverse events			
subjects affected / exposed	395 / 1771 (22.30%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Granulosa cell tumour of the testis			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infantile haemangioma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphoproliferative disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant peritoneal neoplasm				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian epithelial cancer				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retinoblastoma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Aortic stenosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood pressure fluctuation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Deep vein thrombosis				

subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemodynamic instability			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal hypotension			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renovascular hypertension			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subgaleal haematoma			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Venous thrombosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Medically induced preterm birth				
subjects affected / exposed	12 / 1771 (0.68%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
Pregnancy, puerperium and perinatal conditions				
Abnormal labour				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abortion spontaneous				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Amniorrhoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arrested labour				
subjects affected / exposed	9 / 1771 (0.51%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Breech presentation				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			

Caput succedaneum			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cephalhaematoma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cephalo-pelvic disproportion			
subjects affected / exposed	16 / 1771 (0.90%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Cervix dystocia			
subjects affected / exposed	4 / 1771 (0.23%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Eclampsia			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Face presentation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failed induction of labour			
subjects affected / exposed	12 / 1771 (0.68%)		
occurrences causally related to treatment / all	0 / 12		
deaths causally related to treatment / all	0 / 0		
Failed trial of labour			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
False labour			

subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foetal damage			
subjects affected / exposed	5 / 1771 (0.28%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Foetal disorder			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foetal distress syndrome			
subjects affected / exposed	69 / 1771 (3.90%)		
occurrences causally related to treatment / all	0 / 69		
deaths causally related to treatment / all	0 / 0		
Foetal dystocia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal macrosomia			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Foetal hypokinesia			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Foetal growth restriction			
subjects affected / exposed	13 / 1771 (0.73%)		
occurrences causally related to treatment / all	1 / 13		
deaths causally related to treatment / all	0 / 0		
Foetal malposition			

subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foetal malpresentation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension			
subjects affected / exposed	22 / 1771 (1.24%)		
occurrences causally related to treatment / all	0 / 22		
deaths causally related to treatment / all	0 / 0		
Gestational diabetes			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
HELLP syndrome			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhage in pregnancy			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
High foetal head			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
High risk infant			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrops foetalis			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxic ischaemic encephalopathy neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypothermia neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Labour complication				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Large for dates baby				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Low birth weight baby				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Maternal death				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Meconium in amniotic fluid				

subjects affected / exposed	6 / 1771 (0.34%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Morning sickness			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructed labour			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Oligohydramnios			
subjects affected / exposed	14 / 1771 (0.79%)		
occurrences causally related to treatment / all	0 / 14		
deaths causally related to treatment / all	0 / 0		
Pelvic haematoma obstetric			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripartum cardiomyopathy			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Placenta praevia			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Placental insufficiency			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Placental polyp			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Polyhydramnios			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia			
subjects affected / exposed	51 / 1771 (2.88%)		
occurrences causally related to treatment / all	0 / 52		
deaths causally related to treatment / all	0 / 0		
Postpartum haemorrhage			
subjects affected / exposed	26 / 1771 (1.47%)		
occurrences causally related to treatment / all	0 / 27		
deaths causally related to treatment / all	0 / 0		
Precipitate labour			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Premature baby			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature labour			
subjects affected / exposed	15 / 1771 (0.85%)		
occurrences causally related to treatment / all	0 / 15		
deaths causally related to treatment / all	0 / 0		
Premature rupture of membranes			
subjects affected / exposed	5 / 1771 (0.28%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Premature separation of placenta			

subjects affected / exposed	8 / 1771 (0.45%)			
occurrences causally related to treatment / all	0 / 8			
deaths causally related to treatment / all	0 / 0			
Prolonged labour				
subjects affected / exposed	43 / 1771 (2.43%)			
occurrences causally related to treatment / all	0 / 43			
deaths causally related to treatment / all	0 / 0			
Prolonged pregnancy				
subjects affected / exposed	7 / 1771 (0.40%)			
occurrences causally related to treatment / all	0 / 7			
deaths causally related to treatment / all	0 / 0			
Prolonged rupture of membranes				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Preterm premature rupture of membranes				
subjects affected / exposed	14 / 1771 (0.79%)			
occurrences causally related to treatment / all	0 / 14			
deaths causally related to treatment / all	0 / 0			
Retained placenta or membranes				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Retained products of conception				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Shoulder dystocia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stillbirth				

subjects affected / exposed	6 / 1771 (0.34%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Small for dates baby				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Threatened labour				
subjects affected / exposed	15 / 1771 (0.85%)			
occurrences causally related to treatment / all	0 / 15			
deaths causally related to treatment / all	0 / 0			
Umbilical cord around neck				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic delivery				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Transverse presentation				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical cord compression				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical cord prolapse				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine hypotonus				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine hypertonus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine contractions during pregnancy				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine atony				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Weight decrease neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Chest pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Crying				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Death neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Developmental delay				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysplasia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Feeling jittery			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised oedema			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperthermia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothermia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inflammation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Macrosomia			

subjects affected / exposed	0 / 1771 (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	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pyrexia				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Sudden infant death syndrome				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden death				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
ABO incompatibility				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic reaction				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood type incompatibility				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Milk allergy				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhesus incompatibility				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Abnormal uterine bleeding				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical dysplasia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enlarged clitoris				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genital labial adhesions				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic haematoma				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Shortened cervix				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vaginal haemorrhage				

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vaginal discharge				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Adenoidal hypertrophy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Apnoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asphyxia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthmatic crisis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspiration			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial obstruction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial hyperreactivity			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Choking			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic respiratory disease			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cough			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cyanosis neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epistaxis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infantile apnoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Laryngeal stenosis				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal aspiration				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal dyspnoea			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal hypoxia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal asphyxia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal pneumothorax			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal pulmonary hypertension			
subjects affected / exposed	0 / 1771 (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 / 1771 (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 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal tachypnoea			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary artery stenosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary vein stenosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary venous hypertension			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary hypertension			

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory depression				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory arrest				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory depth decreased				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stridor				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachypnoea				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wheezing				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Biliary dilatation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholestasis of pregnancy			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Cholestasis			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder rupture				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Apgar score low				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood pressure increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
C-reactive protein increased				

subjects affected / exposed	0 / 1771 (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 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Foetal heart rate decreased			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal monitoring abnormal			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gynaecological examination abnormal			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemoglobin decreased			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis B surface antigen positive			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Male genital examination abnormal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Medical observation			

subjects affected / exposed	2 / 1771 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Oxygen saturation decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Weight decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral test positive				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Abdominal injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle fracture				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder injury				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brachial plexus injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clavicle fracture				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extradural haematoma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Face injury			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failed forceps delivery			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal exposure during delivery			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fracture of clavicle due to birth trauma			

subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple fractures			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perineal injury			
subjects affected / exposed	0 / 1771 (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	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Procedural haemorrhage			

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skull fracture				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural haemorrhage				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tongue injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thermal burn				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic haemorrhage				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Uterine rupture				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine cervical laceration				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound dehiscence				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vulvovaginal injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound haematoma				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Adrenogenital syndrome				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankyloglossia congenital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aplasia cutis congenita				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anomalous pulmonary venous connection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arteriovenous malformation				
subjects affected / exposed	0 / 1771 (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 / 1771 (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 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Biotinidase deficiency				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Branchial cyst				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brachycephaly				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cataract congenital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Choanal atresia				

subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cleft lip			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chordee			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital cerebral cyst			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital choroid plexus cyst			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital cystic kidney disease			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital inguinal hernia			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital ectopic bladder			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital facial diplegia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital great vessel anomaly			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital hydronephrosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital diaphragmatic hernia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital knee dislocation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital laryngeal stridor			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital melanosis			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital musculoskeletal disorder of skull			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital syphilis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital nephrotic syndrome			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital pneumonia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital pyelocaliectasis			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital myasthenic syndrome			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital torticollis			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital toxoplasmosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cryptorchism			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniosynostosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystic fibrosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cytogenetic abnormality			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dextrocardia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Disseminated neonatal herpes simplex			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysmorphism				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ectopic kidney				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythroblastosis foetalis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epispadias				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibromatosis colli of infancy				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glucose-6-phosphate dehydrogenase deficiency				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemangioma congenital				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart disease congenital			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heterotaxia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypospadias			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertelorism			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal malrotation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kidney duplex			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iris coloboma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngomalacia			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Macrocephaly			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Macrostomia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Menkes' syndrome			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Microtia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Micropenis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Micrognathia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Microcephaly			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myotonic dystrophy			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple congenital abnormalities			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal atresia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteochondrodysplasia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteogenesis imperfecta			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penoscrotal fusion			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Penile torsion			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pectus excavatum			

subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polydactyly				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyloric stenosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal hypoplasia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scaphocephaly				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Shone complex				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin hypoplasia				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syringomyelia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syndactyly			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thalassaemia alpha			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Talipes			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trisomy 21			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urachal abnormality			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular malformation			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute left ventricular failure			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arrhythmia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bradycardia foetal			
subjects affected / exposed	4 / 1771 (0.23%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Bradycardia neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiogenic shock			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal arrhythmia			
subjects affected / exposed	0 / 1771 (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	5 / 1771 (0.28%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nonreassuring foetal heart rate pattern			
subjects affected / exposed	7 / 1771 (0.40%)		
occurrences causally related to treatment / all	0 / 7		
deaths causally related to treatment / all	0 / 0		
Pulmonary valve stenosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Right ventricular hypertrophy			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Supraventricular tachycardia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Supravalvular aortic stenosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia foetal				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Ventricular dysfunction				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wolff-Parkinson-White syndrome				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Brain hypoxia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral cyst				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral ventricle dilatation			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Encephalopathy neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Extrapyramidal disorder			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fontanelle bulging			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infant irritability			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypoxic-ischaemic encephalopathy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infantile spasms				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Kernicterus				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intracranial aneurysm				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lacunar stroke				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myoclonus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Monoplegia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neonatal seizure				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Poor sucking reflex				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Seizure like phenomena				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subependymal cyst				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subarachnoid haemorrhage				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tethered cord syndrome				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Unresponsive to stimuli				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia macrocytic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Blood loss anaemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coagulopathy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated intravascular coagulation				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile neutropenia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal anaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic disorder			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypersplenism			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leukocytosis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polycythaemia			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Deafness unilateral			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deafness bilateral			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Retinopathy of prematurity			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		

Abdominal pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal distension				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal fistula				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphagia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Food poisoning				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal pain			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematochezia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhoids			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infantile colic			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Necrotising enterocolitis neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Necrotising colitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obstructive pancreatitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oesophageal stenosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis relapsing			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Volvulus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Ecchymosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema toxicum neonatorum				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erythema multiforme				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Henoch-Schonlein purpura				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melanoderma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical haemorrhage				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder perforation				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hydronephrosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nephrolithiasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvi-ureteric obstruction				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelocaliectasis				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal disorder in pregnancy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cyst			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureteric stenosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Goitre			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			

Retrognathia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rheumatoid arthritis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Trigger finger				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Torticollis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Acarodermatitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess neck				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenovirus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amoebic dysentery			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Amniotic cavity infection			
subjects affected / exposed	11 / 1771 (0.62%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Appendicitis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bacterial infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast abscess			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
COVID-19			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
COVID-19 pneumonia			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis bacterial			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis orbital			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Conjunctivitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Croup infectious			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dacryocystitis			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Device related infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dysentery			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis bacterial			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometritis			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Escherichia bacteraemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Escherichia pyelonephritis			

subjects affected / exposed	0 / 1771 (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	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Exanthema subitum			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis bacterial			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Genital herpes				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes simplex				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impetigo				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				

subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal sepsis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Leishmaniasis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastitis bacterial			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastitis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis aseptic			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Measles			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus bronchiolitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metapneumovirus infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myiasis			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasopharyngitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal pneumonia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Norovirus infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral herpes			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Omphalitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ophthalmia neonatorum			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral candidiasis			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis externa				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Papilloma viral infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periorbital cellulitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pertussis				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pilonidal disease				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia adenoviral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia parainfluenzae viral				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia pneumococcal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia influenzal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural pneumonia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Postpartum sepsis				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Puerperal infection				

subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Puerperal pyrexia			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Rash pustular			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus infection			

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rhinitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rotavirus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Salmonella bacteraemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Streptococcal sepsis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Systemic viral infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syphilis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suspected COVID-19			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroglossal cyst infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheobronchitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical sepsis			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urachal sinus infection			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	11 / 1771 (0.62%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Viral rash			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicella			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral upper respiratory tract infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound sepsis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Carnitine deficiency				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Feeding disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Food intolerance				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypomagnesaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypervolaemia			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malnutrition			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal hypocalcaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Underweight			
subjects affected / exposed	0 / 1771 (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 / 1771 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	RSV MAT Group - Mother	Placebo Group - Infant	RSV MAT Group - Infant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2561 / 3557 (72.00%)	1293 / 1741 (74.27%)	2615 / 3494 (74.84%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Anogenital warts			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Haemangioma			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	5 / 3494 (0.14%)
occurrences (all)	0	2	5
Haemangioma of skin			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Infantile haemangioma			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (0.00%)
occurrences (all)	0	2	0
Lipoma			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Melanocytic naevus			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	1 / 3494 (0.03%)
occurrences (all)	0	3	1
Ocular neoplasm			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Pyogenic granuloma			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Skin papilloma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ulcerated haemangioma			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Xanthogranuloma			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Uterine leiomyoma			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0

Cyanosis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	3 / 3494 (0.09%)
occurrences (all)	0	2	3
Haematoma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Hot flush			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	1	1	0
Hypertension			
subjects affected / exposed	13 / 3557 (0.37%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	13	0	0
Hypotension			
subjects affected / exposed	7 / 3557 (0.20%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	7	1	0
Varicose vein			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Vasodilatation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Blood pressure fluctuation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Essential hypertension			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Haemorrhage			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Hypertensive crisis			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Inferior vena cava syndrome			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0

Raynaud's phenomenon			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Superficial vein thrombosis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	17 / 3557 (0.48%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	17	0	0
Episiotomy			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Pregnancy, puerperium and perinatal conditions			
Birth trauma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Breech presentation			
subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	10	0	0
Caput succedaneum			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	7 / 3494 (0.20%)
occurrences (all)	0	3	7
Cephalhaematoma			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	10 / 3494 (0.29%)
occurrences (all)	0	4	10
Cephalo-pelvic disproportion			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Complication of delivery			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Complication of pregnancy			

subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
False labour			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	6	0	0
Foetal acidosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Foetal distress syndrome			
subjects affected / exposed	18 / 3557 (0.51%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	18	0	0
Foetal growth restriction			
subjects affected / exposed	16 / 3557 (0.45%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	16	0	0
Foetal hypokinesia			
subjects affected / exposed	18 / 3557 (0.51%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	19	0	0
Foetal macrosomia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Foetal malpresentation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Gestational diabetes			
subjects affected / exposed	35 / 3557 (0.98%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	35	0	0
Gestational hypertension			
subjects affected / exposed	42 / 3557 (1.18%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	42	0	0
Haemorrhage in pregnancy			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	4	0	0
Hypothermia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Jaundice neonatal			

subjects affected / exposed	0 / 3557 (0.00%)	70 / 1741 (4.02%)	207 / 3494 (5.92%)
occurrences (all)	0	70	207
Large for dates baby			
subjects affected / exposed	0 / 3557 (0.00%)	9 / 1741 (0.52%)	9 / 3494 (0.26%)
occurrences (all)	0	9	9
Low birth weight baby			
subjects affected / exposed	0 / 3557 (0.00%)	82 / 1741 (4.71%)	151 / 3494 (4.32%)
occurrences (all)	0	82	151
Meconium in amniotic fluid			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	3	0	3
Meconium stain			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	1	1	4
Morning sickness			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Neonatal disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Oligohydramnios			
subjects affected / exposed	25 / 3557 (0.70%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	25	0	0
Placenta praevia			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Placental disorder			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	4	0	0
Polyhydramnios			
subjects affected / exposed	7 / 3557 (0.20%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	8	0	0
Poor weight gain neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Postpartum haemorrhage			

subjects affected / exposed	32 / 3557 (0.90%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	32	0	0
Pre-eclampsia			
subjects affected / exposed	25 / 3557 (0.70%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	25	0	0
Premature baby			
subjects affected / exposed	0 / 3557 (0.00%)	56 / 1741 (3.22%)	153 / 3494 (4.38%)
occurrences (all)	0	56	153
Premature labour			
subjects affected / exposed	84 / 3557 (2.36%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	84	0	0
Premature rupture of membranes			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	6	0	0
Preterm premature rupture of membranes			
subjects affected / exposed	17 / 3557 (0.48%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	17	0	0
Prolonged labour			
subjects affected / exposed	14 / 3557 (0.39%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	14	0	0
Retained placenta or membranes			
subjects affected / exposed	10 / 3557 (0.28%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	10	0	0
Shoulder dystocia			
subjects affected / exposed	7 / 3557 (0.20%)	2 / 1741 (0.11%)	4 / 3494 (0.11%)
occurrences (all)	7	2	4
Small for dates baby			
subjects affected / exposed	0 / 3557 (0.00%)	147 / 1741 (8.44%)	233 / 3494 (6.67%)
occurrences (all)	0	147	233
Threatened labour			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Umbilical cord abnormality			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	3	0	2

Umbilical cord around neck			
subjects affected / exposed	5 / 3557 (0.14%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	5	1	3
Umbilical cord haemorrhage			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Umbilical granuloma			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	12 / 3494 (0.34%)
occurrences (all)	0	4	12
Uterine contractions during pregnancy			
subjects affected / exposed	14 / 3557 (0.39%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	14	0	0
Uterine hypotonus			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Uterine irritability			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Weight decrease neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Abnormal cord insertion			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Abnormal labour			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Afterbirth pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Amniorrhexis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Amniorrhoea			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Arrested labour			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Face presentation			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Failed induction of labour			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Foetal damage			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0
Foetal dystocia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Hyperemesis gravidarum			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Intrapartum haemorrhage			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Labour complication			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Labour pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Meconium abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Obstructed labour			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Placental calcification			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Placental polyp			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Postpartum uterine subinvolution			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Precipitate labour			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Premature separation of placenta			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Prolonged pregnancy			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Prolonged rupture of membranes			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	4	0	0
Retained products of conception			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Subchorionic haemorrhage			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Transverse presentation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Umbilical cord compression			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Uterine atony			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Uterine hypertonus			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Uterine inversion			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Adverse food reaction			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Administration site swelling			
subjects affected / exposed	96 / 3557 (2.70%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	96	0	0
Administration site pain			
subjects affected / exposed	1294 / 3557 (36.38%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1297	0	0
Administration site erythema			
subjects affected / exposed	133 / 3557 (3.74%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	136	0	0
Asthenia			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	7	0	0
Chills			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	5 / 3494 (0.14%)
occurrences (all)	0	2	5
Crying			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	1 / 3494 (0.03%)
occurrences (all)	0	3	1
Cyst			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Developmental delay			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Discomfort			

subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	1094 / 3557 (30.76%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1104	0	0
Feeling jittery			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Fever neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
High-pitched crying			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hyperthermia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Hypertrophy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hypothermia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ill-defined disorder			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Illness			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Influenza like illness			
subjects affected / exposed	2 / 3557 (0.06%)	4 / 1741 (0.23%)	9 / 3494 (0.26%)
occurrences (all)	3	5	14
Injection site bruising			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0

Injection site erythema			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Injection site oedema			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	4	0	2
Injection site pruritus			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Injection site swelling			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Irritability postvaccinal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Macrosomia			
subjects affected / exposed	0 / 3557 (0.00%)	5 / 1741 (0.29%)	4 / 3494 (0.11%)
occurrences (all)	0	5	4
Malaise			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Oedema			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	7 / 3557 (0.20%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	7	0	0
Pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1

Puncture site pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	43 / 3557 (1.21%)	53 / 1741 (3.04%)	129 / 3494 (3.69%)
occurrences (all)	44	60	134
Swelling			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	2 / 3494 (0.06%)
occurrences (all)	0	3	2
Swelling face			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Thirst			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Vaccination site induration			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Vaccination site pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Vessel puncture site pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Scar inflammation			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0

Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Allergy to arthropod bite			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Allergy to arthropod sting			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Allergy to chemicals			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Allergy to vaccine			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Alloimmunisation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Atopy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Drug hypersensitivity			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Food allergy			
subjects affected / exposed	1 / 3557 (0.03%)	6 / 1741 (0.34%)	14 / 3494 (0.40%)
occurrences (all)	1	6	14
Hypersensitivity			
subjects affected / exposed	3 / 3557 (0.08%)	3 / 1741 (0.17%)	7 / 3494 (0.20%)
occurrences (all)	3	3	7
Milk allergy			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	18 / 3494 (0.52%)
occurrences (all)	0	6	18
Multiple allergies			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Rhesus incompatibility			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Seasonal allergy			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	1	1	4
Reproductive system and breast disorders			
Adnexa uteri cyst			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Balanoposthitis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Bilateral breast buds			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Coital bleeding			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Genital blister			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Genital discomfort			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Genital labial adhesions			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	8 / 3494 (0.23%)
occurrences (all)	0	3	8
Genital macule			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Genital ulceration			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Gynaecomastia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ovarian cyst			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	4	0	0
Penile adhesion			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Pruritus genital			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Scrotal swelling			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Testicular retraction			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Vaginal discharge			
subjects affected / exposed	14 / 3557 (0.39%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	15	2	1
Vaginal disorder			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	3	0	1
Vaginal haemorrhage			
subjects affected / exposed	17 / 3557 (0.48%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	17	0	1
Vulval oedema			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal pain			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal pruritus			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Abnormal uterine bleeding			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Bartholin's cyst			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Breast engorgement			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Breast inflammation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Breast mass			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Breast pain			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Cystocele			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Endometrial hyperplasia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Female genital tract fistula			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Genital haemorrhage			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Heavy menstrual bleeding			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Intermenstrual bleeding			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Lactation disorder			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Lactation insufficiency			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Nipple disorder			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Perineal pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Shortened cervix			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Threatened uterine rupture			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Uterine haemorrhage			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Uterine prolapse			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Uterine scar			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Apnoea			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Apnoeic attack			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	2 / 3557 (0.06%)	6 / 1741 (0.34%)	8 / 3494 (0.23%)
occurrences (all)	2	6	8
Asthmatic crisis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Atelectasis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Bronchospasm			
subjects affected / exposed	0 / 3557 (0.00%)	10 / 1741 (0.57%)	12 / 3494 (0.34%)
occurrences (all)	0	12	14
Bronchitis chronic			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Bronchiolitis obliterans syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Brief resolved unexplained event			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Bronchial hyperreactivity			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	8 / 3494 (0.23%)
occurrences (all)	0	4	9
Bronchial obstruction			
subjects affected / exposed	0 / 3557 (0.00%)	5 / 1741 (0.29%)	20 / 3494 (0.57%)
occurrences (all)	0	6	31
Catarrh			

subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	7 / 3494 (0.20%)
occurrences (all)	0	9	11
Childhood asthma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Choking			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Cough			
subjects affected / exposed	10 / 3557 (0.28%)	82 / 1741 (4.71%)	180 / 3494 (5.15%)
occurrences (all)	10	109	251
Dysphonia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Dyspnoea			
subjects affected / exposed	3 / 3557 (0.08%)	13 / 1741 (0.75%)	18 / 3494 (0.52%)
occurrences (all)	4	15	21
Epistaxis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hyperventilation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Increased bronchial secretion			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Infantile apnoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Lower respiratory tract congestion			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Meconium aspiration syndrome			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Nasal congestion			
subjects affected / exposed	4 / 3557 (0.11%)	57 / 1741 (3.27%)	142 / 3494 (4.06%)
occurrences (all)	4	64	160
Nasal discomfort			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Nasal disorder			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	6 / 3494 (0.17%)
occurrences (all)	0	4	7
Nasal dryness			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Nasal inflammation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Nasal obstruction			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	6 / 3494 (0.17%)
occurrences (all)	0	2	8
Neonatal respiratory depression			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	0 / 3494 (0.00%)
occurrences (all)	0	3	0
Neonatal respiratory distress			
subjects affected / exposed	0 / 3557 (0.00%)	7 / 1741 (0.40%)	12 / 3494 (0.34%)
occurrences (all)	0	7	12
Neonatal tachypnoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Oropharyngeal pain			
subjects affected / exposed	5 / 3557 (0.14%)	2 / 1741 (0.11%)	0 / 3494 (0.00%)
occurrences (all)	5	2	0
Pharyngeal erythema			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pneumothorax			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	3 / 3557 (0.08%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	3	1	5
Pulmonary artery stenosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Pulmonary congestion			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	1	0	1
Pulmonary hypertension			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Respiration abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Respiratory depression			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Respiratory disorder			
subjects affected / exposed	6 / 3557 (0.17%)	72 / 1741 (4.14%)	141 / 3494 (4.04%)
occurrences (all)	6	162	343
Respiratory distress			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Respiratory symptom			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Rhinitis allergic			
subjects affected / exposed	2 / 3557 (0.06%)	7 / 1741 (0.40%)	19 / 3494 (0.54%)
occurrences (all)	2	8	21
Rhinorrhoea			
subjects affected / exposed	3 / 3557 (0.08%)	51 / 1741 (2.93%)	120 / 3494 (3.43%)
occurrences (all)	3	80	191
Rhonchi			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Sinonasal obstruction			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	0	1	4
Sinus congestion			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	1	0	1
Sneezing			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Stridor			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Tachypnoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (0.14%)
occurrences (all)	0	1	5
Tracheomalacia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 3557 (0.00%)	8 / 1741 (0.46%)	12 / 3494 (0.34%)
occurrences (all)	0	8	12
Upper respiratory tract congestion			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Vasomotor rhinitis			
subjects affected / exposed	0 / 3557 (0.00%)	7 / 1741 (0.40%)	7 / 3494 (0.20%)
occurrences (all)	0	11	8
Wheezing			
subjects affected / exposed	1 / 3557 (0.03%)	15 / 1741 (0.86%)	23 / 3494 (0.66%)
occurrences (all)	1	16	24
Immature respiratory system			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Nasal turbinate hypertrophy			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Nasal ulcer			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	7 / 3557 (0.20%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	7	0	0
Brief psychotic disorder, with postpartum onset			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	4	0	0
Irritability			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (0.14%)
occurrences (all)	0	1	5
Panic attack			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Psychomotor retardation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Selective eating disorder			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Sleep disorder			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Tearfulness			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Perinatal depression			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	6	0	0
Postpartum anxiety			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Cholestasis of pregnancy			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	14 / 1741 (0.80%)	27 / 3494 (0.77%)
occurrences (all)	0	14	27
Hypertransaminasaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Jaundice			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Biliary colic			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0

Cholecystitis chronic			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Investigations			
Acoustic stimulation tests abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (0.14%)
occurrences (all)	0	1	5
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Apgar score low			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Audiogram abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Blood glucose decreased			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences (all)	0	3	4
Blood glucose increased			
subjects affected / exposed	3 / 3557 (0.08%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	3	1	0
Blood iron decreased			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Blood potassium increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Blood pressure increased			

subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Blood thyroid stimulating hormone abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Body temperature increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
C-reactive protein increased			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur			
subjects affected / exposed	0 / 3557 (0.00%)	11 / 1741 (0.63%)	28 / 3494 (0.80%)
occurrences (all)	0	11	28
Cardiac murmur functional			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Coombs direct test positive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Coombs test positive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Drug screen positive			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	1	0	1
Electroencephalogram normal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
HIV test positive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0

Haemoglobin decreased			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	1	0	1
Head circumference abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Heart rate increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Human rhinovirus test positive			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Immunoreactive trypsinogen increased			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Influenza A virus test positive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Medical observation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Otoacoustic emissions test abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Oxygen saturation decreased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Serum ferritin decreased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Vitamin B12 decreased			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (0.14%)
occurrences (all)	0	1	5
Weight increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Foetal heart rate abnormal			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Foetal heart rate increased			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Foetal heart rate indeterminate			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Foetal monitoring			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Foetal monitoring abnormal			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0
Foetal non-stress test abnormal			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Inhibin A increased			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Kleihauer-Betke test positive			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accidental exposure to product packaging			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Anal injury			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	1	1	1
Arthropod bite			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences (all)	0	4	4
Animal scratch			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Animal bite			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	1	0	2
Bone fissure			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Burns first degree			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Chemical burn			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Clavicle fracture			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	5 / 3494 (0.14%)
occurrences (all)	0	0	5
Contusion			
subjects affected / exposed	1 / 3557 (0.03%)	2 / 1741 (0.11%)	5 / 3494 (0.14%)
occurrences (all)	1	2	5
Craniocerebral injury			

subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	3 / 3494 (0.09%)
occurrences (all)	0	4	3
Eye injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Face injury			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Fall			
subjects affected / exposed	6 / 3557 (0.17%)	5 / 1741 (0.29%)	7 / 3494 (0.20%)
occurrences (all)	6	5	7
Femur fracture			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Foreign body ingestion			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Fracture of clavicle due to birth trauma			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (0.00%)
occurrences (all)	0	2	0
Head injury			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	9 / 3494 (0.26%)
occurrences (all)	0	2	9
Humerus fracture			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Immunisation reaction			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	1	1	2
Incision site rash			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Injury			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	2	0

Joint dislocation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Joint injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Limb injury			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	1	1	2
Lip injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Mouth injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Muscle strain			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Nasal injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Perineal injury			
subjects affected / exposed	71 / 3557 (2.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	71	0	0
Post vaccination fever			
subjects affected / exposed	1 / 3557 (0.03%)	3 / 1741 (0.17%)	3 / 3494 (0.09%)
occurrences (all)	1	3	3
Procedural complication			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Radial head dislocation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1

Road traffic accident			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	3	0	2
Scar			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Skin injury			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Skin laceration			
subjects affected / exposed	2 / 3557 (0.06%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	2	1	3
Skin wound			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Soft tissue injury			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	1	1	2
Ulnar nerve injury			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Abdominal injury			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Anaemia postoperative			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Arthropod sting			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0

Foot fracture			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Incision site dermatitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Incision site haemorrhage			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Incision site pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Post procedural complication			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Post procedural fever			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Post procedural haemorrhage			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Postoperative wound complication			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Procedural headache			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Seroma			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Tooth fracture			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Urethral injury			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0

Uterine cervical laceration			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal injury			
subjects affected / exposed	45 / 3557 (1.27%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	45	0	0
Wound dehiscence			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Accessory auricle			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Albinism			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Anorectal malformation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Anomaly of external ear congenital			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ankyloglossia congenital			
subjects affected / exposed	0 / 3557 (0.00%)	23 / 1741 (1.32%)	51 / 3494 (1.46%)
occurrences (all)	0	23	51
Atrial septal defect			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	1	1	3
Birth mark			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Carnitine-acylcarnitine translocase deficiency			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Cleft uvula			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Congenital hypothyroidism			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Congenital melanosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Congenital musculoskeletal disorder of skull			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Congenital naevus			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Congenital skin dimples			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	7 / 3494 (0.20%)
occurrences (all)	0	3	7
Congenital syphilis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Congenital thymus absence			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Congenital umbilical hernia			
subjects affected / exposed	0 / 3557 (0.00%)	21 / 1741 (1.21%)	42 / 3494 (1.20%)
occurrences (all)	0	21	42
Craniosynostosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Cryptorchism			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	6 / 3494 (0.17%)
occurrences (all)	0	0	6
Cystic fibrosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1

Dacryostenosis congenital			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Dermoid cyst			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Ear malformation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Fibromatosis colli of infancy			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Glucose-6-phosphate dehydrogenase deficiency			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Haemangioma congenital			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	11 / 3494 (0.31%)
occurrences (all)	0	1	11
Heart disease congenital			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hydrocele			
subjects affected / exposed	0 / 3557 (0.00%)	5 / 1741 (0.29%)	11 / 3494 (0.31%)
occurrences (all)	0	5	11
Labial tie			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	0	1	3
Laryngomalacia			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	6 / 3494 (0.17%)
occurrences (all)	0	2	6
Low set ears			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Lymphatic malformation			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Naevus flammeus			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	7 / 3494 (0.20%)
occurrences (all)	0	1	7
Patent ductus arteriosus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Phimosis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	7 / 3494 (0.20%)
occurrences (all)	0	2	7
Polydactyly			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Preauricular cyst			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	0	1	4
Pulmonary artery stenosis congenital			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Sickle cell anaemia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	0	1	3
Sickle cell disease			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Stahl's ear			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Thalassaemia alpha			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Ventricular septal defect			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Congenital hydronephrosis			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Congenital renal cyst			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Bradycardia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Bradycardia foetal			
subjects affected / exposed	7 / 3557 (0.20%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	7	0	2
Bradycardia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	0	1	3
Extrasystoles			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	1	0	1
Foetal arrhythmia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Foetal heart rate deceleration abnormality			
subjects affected / exposed	7 / 3557 (0.20%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	7	1	0
Left ventricular dilatation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Mitral valve incompetence			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Neonatal tachycardia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Palpitations			

subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	6 / 3557 (0.17%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	6	1	0
Tachycardia foetal			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	3	0	1
Ventricular hypertrophy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Nonreassuring foetal heart rate pattern			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Ventricular extrasystoles			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Agitation neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Brain oedema			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Burning sensation			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Carpal tunnel syndrome			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Cerebral haemorrhage			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0
Drooling			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Facial paralysis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Febrile convulsion			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	1 / 3494 (0.03%)
occurrences (all)	0	4	1
Fontanelle depressed			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Gross motor delay			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Haemorrhage intracranial			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	962 / 3557 (27.05%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	993	0	0
Hypertonia			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	8 / 3494 (0.23%)
occurrences (all)	0	2	8
Hypotonia			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	8 / 3494 (0.23%)
occurrences (all)	0	4	9
IVth nerve paralysis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1

Infant irritability			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Language disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Lethargy			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Migraine			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	6	0	0
Motor developmental delay			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Movement disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Myoclonus			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Nerve compression			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Neurodevelopmental delay			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Nystagmus			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Paraesthesia			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Presyncope			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0

Sciatica			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	4	0	0
Seizure			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Seizure like phenomena			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Subependymal cyst			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Tethered cord syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Tremor neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Lumbar radiculopathy			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Neuralgia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Sensory loss			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0

Tension headache			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia of pregnancy			
subjects affected / exposed	14 / 3557 (0.39%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	14	0	0
Anaemia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Anaemia			
subjects affected / exposed	62 / 3557 (1.74%)	12 / 1741 (0.69%)	33 / 3494 (0.94%)
occurrences (all)	62	12	34
Bandaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Haemorrhagic disease of newborn			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Hypochromic anaemia			
subjects affected / exposed	1 / 3557 (0.03%)	5 / 1741 (0.29%)	14 / 3494 (0.40%)
occurrences (all)	1	5	14
Iron deficiency anaemia			
subjects affected / exposed	4 / 3557 (0.11%)	2 / 1741 (0.11%)	6 / 3494 (0.17%)
occurrences (all)	4	2	6
Leukopenia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Lymph node pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	4	0	1
Microcytic anaemia			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences (all)	0	0	4
Neutropenia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Polycythaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	1	1	2
Thrombocytopenia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Blood loss anaemia			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0
Coagulopathy			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Leukocytosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Normochromic normocytic anaemia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Normocytic anaemia			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Ear pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences (all)	1	0	5

Eustachian tube dysfunction			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Excessive cerumen production			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Middle ear inflammation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Otorrhoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Tympanic membrane disorder			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Tympanic membrane hyperaemia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Tinnitus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Amblyopia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Blepharitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Chalazion			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Conjunctival haemorrhage			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	6 / 3494 (0.17%)
occurrences (all)	0	2	6
Conjunctival hyperaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Conjunctivitis allergic			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Corneal erosion			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 3557 (0.00%)	12 / 1741 (0.69%)	10 / 3494 (0.29%)
occurrences (all)	0	13	10
Dry eye			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Eye discharge			
subjects affected / exposed	0 / 3557 (0.00%)	8 / 1741 (0.46%)	4 / 3494 (0.11%)
occurrences (all)	0	8	4
Eye inflammation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Eye swelling			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Eyelid ptosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Orbital oedema			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Periorbital oedema			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Strabismus			

subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	2 / 3494 (0.06%)
occurrences (all)	0	3	2
Swelling of eyelid			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Trichiasis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Eczema eyelids			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	3 / 3557 (0.08%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	3	2	2
Abdominal pain upper			
subjects affected / exposed	7 / 3557 (0.20%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	7	1	1
Abdominal pain lower			
subjects affected / exposed	20 / 3557 (0.56%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	22	0	0
Abdominal pain			
subjects affected / exposed	508 / 3557 (14.28%)	11 / 1741 (0.63%)	22 / 3494 (0.63%)
occurrences (all)	512	11	22
Abdominal hernia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Abdominal distension			

subjects affected / exposed	1 / 3557 (0.03%)	4 / 1741 (0.23%)	2 / 3494 (0.06%)
occurrences (all)	1	4	2
Allergic colitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Anal rash			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Anal fissure			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	1	0	2
Anal erythema			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Anal eczema			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Aphthous ulcer			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Colitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	11 / 3557 (0.31%)	23 / 1741 (1.32%)	64 / 3494 (1.83%)
occurrences (all)	12	24	66
Constipation neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	357 / 3557 (10.04%)	41 / 1741 (2.35%)	97 / 3494 (2.78%)
occurrences (all)	361	44	107
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1

Dyschezia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Dyspepsia			
subjects affected / exposed	15 / 3557 (0.42%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	15	0	1
Dysphagia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Enlarged uvula			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Enteritis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Enterocolitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Eosinophilic colitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	2 / 3557 (0.06%)	6 / 1741 (0.34%)	11 / 3494 (0.31%)
occurrences (all)	2	6	12
Food poisoning			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	1	1	1
Frequent bowel movements			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	3 / 3557 (0.08%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	3	1	1
Gastrointestinal disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	2

Gastrooesophageal reflux disease			
subjects affected / exposed	8 / 3557 (0.22%)	46 / 1741 (2.64%)	76 / 3494 (2.18%)
occurrences (all)	9	48	78
Gastrooesophageal reflux in neonate			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Gingival cyst			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Haematemesis			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	1	1	0
Haematochezia			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences (all)	0	3	4
Haemorrhoids			
subjects affected / exposed	21 / 3557 (0.59%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	22	0	0
Haemorrhoids thrombosed			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Hyperchlorhydria			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Infantile colic			
subjects affected / exposed	0 / 3557 (0.00%)	12 / 1741 (0.69%)	15 / 3494 (0.43%)
occurrences (all)	0	12	15
Infantile spitting up			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	0 / 3494 (0.00%)
occurrences (all)	0	3	0
Inguinal hernia			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	4 / 3494 (0.11%)
occurrences (all)	0	2	4
Meconium plug syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1

Mouth ulceration			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	606 / 3557 (17.04%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	613	1	0
Oesophagitis			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	1	1	0
Oral disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Peptic ulcer			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Proctitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Rectal prolapse			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Regurgitation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (0.14%)
occurrences (all)	0	1	5
Stomatitis			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences (all)	0	3	4
Teething			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	11 / 3494 (0.31%)
occurrences (all)	0	6	11
Tooth demineralisation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Tooth development disorder			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Toothache			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Umbilical hernia			
subjects affected / exposed	0 / 3557 (0.00%)	8 / 1741 (0.46%)	15 / 3494 (0.43%)
occurrences (all)	0	8	15
Vomiting			
subjects affected / exposed	287 / 3557 (8.07%)	26 / 1741 (1.49%)	49 / 3494 (1.40%)
occurrences (all)	291	26	51
Vomiting projectile			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Anal incontinence			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Ileus			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Odynophagia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Pelvic floor dysfunction			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne infantile			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	7 / 3494 (0.20%)
occurrences (all)	0	1	7
Alopecia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Blister			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	1	1	2

Cafe au lait spots			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Cellulite			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Dermal cyst			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Dermatitis			
subjects affected / exposed	2 / 3557 (0.06%)	15 / 1741 (0.86%)	35 / 3494 (1.00%)
occurrences (all)	2	15	35
Dermatitis allergic			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	1	1	3
Dermatitis atopic			
subjects affected / exposed	0 / 3557 (0.00%)	42 / 1741 (2.41%)	56 / 3494 (1.60%)
occurrences (all)	0	44	58
Dermatitis contact			
subjects affected / exposed	1 / 3557 (0.03%)	2 / 1741 (0.11%)	10 / 3494 (0.29%)
occurrences (all)	1	2	10
Dermatitis diaper			
subjects affected / exposed	0 / 3557 (0.00%)	55 / 1741 (3.16%)	113 / 3494 (3.23%)
occurrences (all)	0	58	124
Drug eruption			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	6 / 3494 (0.17%)
occurrences (all)	0	1	6
Eczema			
subjects affected / exposed	4 / 3557 (0.11%)	34 / 1741 (1.95%)	76 / 3494 (2.18%)
occurrences (all)	4	37	76

Eczema asteatotic			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Eczema infantile			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	2 / 3494 (0.06%)
occurrences (all)	0	4	2
Eczema nummular			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Erythema			
subjects affected / exposed	1 / 3557 (0.03%)	3 / 1741 (0.17%)	2 / 3494 (0.06%)
occurrences (all)	1	4	2
Erythema toxicum neonatorum			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	5 / 3494 (0.14%)
occurrences (all)	0	2	5
Hand dermatitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Herpes gestationis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ingrowing nail			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	5 / 3494 (0.14%)
occurrences (all)	0	0	5
Intertrigo			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Macule			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Melanoderma			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1

Milia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Miliaria			
subjects affected / exposed	0 / 3557 (0.00%)	15 / 1741 (0.86%)	33 / 3494 (0.94%)
occurrences (all)	0	15	35
Nail fold inflammation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Papule			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Perioral dermatitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Petechiae			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pigmentation disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Pityriasis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pityriasis alba			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	0	1	3
Pityriasis rosea			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Prurigo			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Pruritus			
subjects affected / exposed	8 / 3557 (0.22%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	9	0	0

Rash			
subjects affected / exposed	2 / 3557 (0.06%)	24 / 1741 (1.38%)	53 / 3494 (1.52%)
occurrences (all)	2	27	53
Rash erythematous			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Rash neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Rash papular			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	6 / 3494 (0.17%)
occurrences (all)	0	0	6
Rash pruritic			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Seborrhoea			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 3557 (0.00%)	27 / 1741 (1.55%)	72 / 3494 (2.06%)
occurrences (all)	0	27	72
Skin exfoliation			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	0 / 3494 (0.00%)
occurrences (all)	0	3	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Skin hypopigmentation			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2

Skin irritation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Skin lesion			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	0	1	4
Skin mass			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Skin ulcer			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Solar dermatitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Toxic skin eruption			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Transient neonatal pustular melanosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Umbilical discharge			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	4 / 3557 (0.11%)	2 / 1741 (0.11%)	6 / 3494 (0.17%)
occurrences (all)	5	2	6
Urticaria papular			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Vitiligo			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Acne			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Excessive granulation tissue			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Polymorphic eruption of pregnancy			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Prurigo of pregnancy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Skin reaction			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	4	0	1
Haematuria			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hydronephrosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Oliguria			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0

Proteinuria			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	4	0	0
Pyelocaliectasis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	0	1	3
Renal colic			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Urinary hesitation			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Vesicoureteric reflux			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Atonic urinary bladder			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Bladder spasm			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Urinary retention			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Precocious puberty			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Thyroid dysfunction in pregnancy			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Transient neonatal hyperthyrotropinaemia			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Acquired plagiocephaly			
subjects affected / exposed	0 / 3557 (0.00%)	10 / 1741 (0.57%)	21 / 3494 (0.60%)
occurrences (all)	0	10	21
Arthralgia			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Asymmetric gluteal fold			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Asymmetric thigh fold			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Axillary mass			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	21 / 3557 (0.59%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	22	0	0
Bone hypertrophy			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Bone disorder			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Foot deformity			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Head deformity			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	4 / 3494 (0.11%)
occurrences (all)	0	2	4
Hypertonia neonatal			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Hypotonia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Joint laxity			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Joint noise			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ligament laxity			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Ligament pain			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	8 / 3557 (0.22%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	8	1	0
Muscle twitching			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Muscular weakness			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal disorder			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	4 / 3557 (0.11%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	4	0	1
Newborn head moulding			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Nose deformity			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Posture abnormal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pubic pain			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Short stature			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Snapping hip syndrome			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Tendon disorder			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Torticollis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	10 / 3494 (0.29%)
occurrences (all)	0	2	10
Coccydynia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Costochondritis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Neck pain			

subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Plantar fasciitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	1 / 3557 (0.03%)	13 / 1741 (0.75%)	29 / 3494 (0.83%)
occurrences (all)	1	15	34
Abscess limb			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	1	1	4
Abscess			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Acute sinusitis			
subjects affected / exposed	2 / 3557 (0.06%)	4 / 1741 (0.23%)	5 / 3494 (0.14%)
occurrences (all)	2	4	6
Adenovirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	4 / 3494 (0.11%)
occurrences (all)	0	2	4
Adenoviral upper respiratory infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Anal candidiasis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Anal abscess			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Amoebic dysentery			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	3
Amniotic cavity infection			
subjects affected / exposed	18 / 3557 (0.51%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	18	0	0
Ascariasis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Balanitis candida			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Asymptomatic bacteriuria			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	3	0	1
Bacterial disease carrier			
subjects affected / exposed	27 / 3557 (0.76%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	27	0	0
Bacterial vaginosis			
subjects affected / exposed	12 / 3557 (0.34%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	12	0	0
Bartholin's abscess			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Beta haemolytic streptococcal infection			
subjects affected / exposed	5 / 3557 (0.14%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	5	1	1
Breast abscess			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Body tinea			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	5 / 3494 (0.14%)
occurrences (all)	0	6	5
Candida infection			
subjects affected / exposed	4 / 3557 (0.11%)	10 / 1741 (0.57%)	16 / 3494 (0.46%)
occurrences (all)	4	11	17

Candida nappy rash			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	9 / 3494 (0.26%)
occurrences (all)	0	2	10
COVID-19			
subjects affected / exposed	117 / 3557 (3.29%)	90 / 1741 (5.17%)	159 / 3494 (4.55%)
occurrences (all)	118	90	161
Bullous impetigo			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Bronchitis			
subjects affected / exposed	2 / 3557 (0.06%)	38 / 1741 (2.18%)	82 / 3494 (2.35%)
occurrences (all)	2	43	97
Bronchiolitis			
subjects affected / exposed	0 / 3557 (0.00%)	152 / 1741 (8.73%)	298 / 3494 (8.53%)
occurrences (all)	0	175	387
Cellulitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	1	0	1
Cellulitis orbital			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Conjunctivitis			
subjects affected / exposed	4 / 3557 (0.11%)	61 / 1741 (3.50%)	141 / 3494 (4.04%)
occurrences (all)	4	71	148
Conjunctivitis bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	11 / 3494 (0.31%)
occurrences (all)	0	6	11
Conjunctivitis viral			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	4 / 3494 (0.11%)
occurrences (all)	0	2	4
Croup infectious			
subjects affected / exposed	0 / 3557 (0.00%)	12 / 1741 (0.69%)	24 / 3494 (0.69%)
occurrences (all)	0	13	28
Cystitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0

Dacryocystitis			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	3 / 3494 (0.09%)
occurrences (all)	0	2	3
Dengue fever			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Dermatitis infected			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	3
Dermatophytosis of nail			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Diarrhoea infectious			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Dysentery			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Ear infection			
subjects affected / exposed	2 / 3557 (0.06%)	63 / 1741 (3.62%)	120 / 3494 (3.43%)
occurrences (all)	2	83	148
Ear infection viral			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Eczema impetiginous			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Eczema infected			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Enterobiasis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Enterovirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	4 / 3494 (0.11%)
occurrences (all)	0	2	4

Erysipelas			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Erythema infectiosum			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Escherichia infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Exanthema subitum			
subjects affected / exposed	0 / 3557 (0.00%)	12 / 1741 (0.69%)	16 / 3494 (0.46%)
occurrences (all)	0	12	16
Eye infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (0.14%)
occurrences (all)	0	1	5
Eye infection staphylococcal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Eye infection viral			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Eyelid infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	4 / 3557 (0.11%)	3 / 1741 (0.17%)	2 / 3494 (0.06%)
occurrences (all)	4	3	2
Fungal skin infection			
subjects affected / exposed	2 / 3557 (0.06%)	8 / 1741 (0.46%)	16 / 3494 (0.46%)
occurrences (all)	2	9	16

Furuncle			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	2 / 3494 (0.06%)
occurrences (all)	0	1	2
Gastroenteritis			
subjects affected / exposed	13 / 3557 (0.37%)	60 / 1741 (3.45%)	104 / 3494 (2.98%)
occurrences (all)	13	68	119
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Gastroenteritis bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Gastroenteritis norovirus			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	6 / 3557 (0.17%)	5 / 1741 (0.29%)	14 / 3494 (0.40%)
occurrences (all)	6	5	15
Gastrointestinal infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal viral infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Genital candidiasis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Genital herpes			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Groin abscess			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Groin infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0

Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 3557 (0.03%)	12 / 1741 (0.69%)	38 / 3494 (1.09%)
occurrences (all)	1	12	38
Herpangina			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	6 / 3494 (0.17%)
occurrences (all)	0	1	6
Herpes simplex			
subjects affected / exposed	2 / 3557 (0.06%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	2	1	0
Herpes virus infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Hordeolum			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Human herpesvirus 6 infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 3557 (0.00%)	11 / 1741 (0.63%)	27 / 3494 (0.77%)
occurrences (all)	0	11	27
Infected bite			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	7 / 3557 (0.20%)	14 / 1741 (0.80%)	24 / 3494 (0.69%)
occurrences (all)	7	14	24
Klebsiella urinary tract infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1

Labyrinthitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 3557 (0.00%)	16 / 1741 (0.92%)	45 / 3494 (1.29%)
occurrences (all)	0	17	51
Laryngotracheitis obstructive			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Localised infection			
subjects affected / exposed	1 / 3557 (0.03%)	2 / 1741 (0.11%)	0 / 3494 (0.00%)
occurrences (all)	1	2	0
Lower respiratory tract infection			
subjects affected / exposed	4 / 3557 (0.11%)	60 / 1741 (3.45%)	124 / 3494 (3.55%)
occurrences (all)	4	72	144
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 3557 (0.00%)	7 / 1741 (0.40%)	8 / 3494 (0.23%)
occurrences (all)	0	7	8
Mastitis			
subjects affected / exposed	42 / 3557 (1.18%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	42	0	0
Metapneumovirus bronchiolitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Metapneumovirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	3 / 3494 (0.09%)
occurrences (all)	0	0	3
Myringitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Nail bed infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	38 / 3557 (1.07%)	306 / 1741 (17.58%)	590 / 3494 (16.89%)
occurrences (all)	41	557	1121

Neonatal infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Neonatal pneumonia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Norovirus infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Omphalitis			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	4 / 3494 (0.11%)
occurrences (all)	0	4	4
Ophthalmia neonatorum			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	6 / 3494 (0.17%)
occurrences (all)	0	2	6
Oral candidiasis			
subjects affected / exposed	0 / 3557 (0.00%)	30 / 1741 (1.72%)	51 / 3494 (1.46%)
occurrences (all)	0	34	57
Oral fungal infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Oral herpes			
subjects affected / exposed	5 / 3557 (0.14%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	5	2	2
Oral viral infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	4 / 3494 (0.11%)
occurrences (all)	2	0	4
Otitis externa fungal			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	1 / 3557 (0.03%)	59 / 1741 (3.39%)	114 / 3494 (3.26%)
occurrences (all)	1	79	141

Otitis media acute			
subjects affected / exposed	0 / 3557 (0.00%)	45 / 1741 (2.58%)	98 / 3494 (2.80%)
occurrences (all)	0	55	113
Otitis media chronic			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Parainfluenzae virus infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	5 / 3494 (0.14%)
occurrences (all)	0	1	5
Parasitic gastroenteritis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Paronychia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	0	1	4
Periodontitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Pertussis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	5 / 3557 (0.14%)	14 / 1741 (0.80%)	39 / 3494 (1.12%)
occurrences (all)	5	14	40
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	1 / 3494 (0.03%)
occurrences (all)	0	2	1
Pharyngotonsillitis			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	9 / 3494 (0.26%)
occurrences (all)	0	4	10
Pneumonia			
subjects affected / exposed	0 / 3557 (0.00%)	10 / 1741 (0.57%)	31 / 3494 (0.89%)
occurrences (all)	0	10	31
Pneumonia bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1

Pneumonia mycoplasmal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pneumonia viral			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pustule			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Pyoderma			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	4 / 3494 (0.11%)
occurrences (all)	0	3	6
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 3557 (0.00%)	25 / 1741 (1.44%)	22 / 3494 (0.63%)
occurrences (all)	0	25	23
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	4 / 3494 (0.11%)
occurrences (all)	0	4	4
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 3557 (0.00%)	18 / 1741 (1.03%)	34 / 3494 (0.97%)
occurrences (all)	0	18	34
Respiratory tract infection			
subjects affected / exposed	51 / 3557 (1.43%)	65 / 1741 (3.73%)	140 / 3494 (4.01%)
occurrences (all)	55	131	243
Respiratory tract infection viral			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	4 / 3494 (0.11%)
occurrences (all)	0	7	4
Rhinitis			
subjects affected / exposed	0 / 3557 (0.00%)	46 / 1741 (2.64%)	86 / 3494 (2.46%)
occurrences (all)	0	50	96
Rhinovirus infection			

subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	10 / 3494 (0.29%)
occurrences (all)	0	3	12
Roseola			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Scarlet fever			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	1	1	0
Sepsis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Sepsis neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	0 / 3494 (0.00%)
occurrences (all)	0	2	0
Sinusitis			
subjects affected / exposed	7 / 3557 (0.20%)	6 / 1741 (0.34%)	9 / 3494 (0.26%)
occurrences (all)	8	8	9
Skin candida			
subjects affected / exposed	0 / 3557 (0.00%)	8 / 1741 (0.46%)	4 / 3494 (0.11%)
occurrences (all)	0	8	4
Skin infection			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	0	1	4
Staphylococcal infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Subcutaneous abscess			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	5 / 3494 (0.14%)
occurrences (all)	0	4	5
Subglottic laryngitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Suspected COVID-19			
subjects affected / exposed	10 / 3557 (0.28%)	18 / 1741 (1.03%)	59 / 3494 (1.69%)
occurrences (all)	10	19	61
Systemic viral infection			

subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	6 / 3494 (0.17%)
occurrences (all)	0	3	6
Thyroglossal cyst infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Tinea capitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Tinea infection			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	5 / 3494 (0.14%)
occurrences (all)	0	2	5
Tinea pedis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Tinea versicolour			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	3 / 3494 (0.09%)
occurrences (all)	0	3	3
Tonsillitis			
subjects affected / exposed	2 / 3557 (0.06%)	8 / 1741 (0.46%)	14 / 3494 (0.40%)
occurrences (all)	2	8	14
Toxoplasmosis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Tracheitis			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	0	1	1
Tracheobronchitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	71 / 3557 (2.00%)	396 / 1741 (22.75%)	848 / 3494 (24.27%)
occurrences (all)	86	779	1703
Upper respiratory tract infection bacterial			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2

Urinary tract infection			
subjects affected / exposed	104 / 3557 (2.92%)	9 / 1741 (0.52%)	29 / 3494 (0.83%)
occurrences (all)	107	9	32
Urogenital infection fungal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Vaccination site abscess			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Vaginal infection			
subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	9	0	1
Varicella			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	8 / 3494 (0.23%)
occurrences (all)	0	4	8
Viral diarrhoea			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	0	0	2
Viral infection			
subjects affected / exposed	0 / 3557 (0.00%)	12 / 1741 (0.69%)	36 / 3494 (1.03%)
occurrences (all)	0	12	37
Viral pharyngitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	2 / 3494 (0.06%)
occurrences (all)	1	0	2
Viral rash			
subjects affected / exposed	0 / 3557 (0.00%)	11 / 1741 (0.63%)	22 / 3494 (0.63%)
occurrences (all)	0	11	22
Viral rhinitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Viral tonsillitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 3557 (0.06%)	24 / 1741 (1.38%)	43 / 3494 (1.23%)
occurrences (all)	2	37	55

Vulvitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	13 / 3557 (0.37%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	13	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	6	0	0
Wound infection			
subjects affected / exposed	2 / 3557 (0.06%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	2	1	0
Bacterial vulvovaginitis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
COVID-19 pneumonia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Cervicitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Endometritis			
subjects affected / exposed	5 / 3557 (0.14%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	5	0	0
Enterococcal infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Genital herpes simplex			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Genital infection female			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0

Gingivitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Gonococcal infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Hepatitis B			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Kidney infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Mastitis postpartum			
subjects affected / exposed	3 / 3557 (0.08%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	3	0	0
Otosalpingitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Perineal infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Postoperative wound infection			
subjects affected / exposed	10 / 3557 (0.28%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	10	0	0
Puerperal infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Puerperal pyrexia			
subjects affected / exposed	6 / 3557 (0.17%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	6	0	0
Syphilis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0

Tooth infection			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Uterine infection			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Vulval abscess			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Vulvovaginitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Vulvovaginitis trichomonal			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Wound cellulitis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Wound sepsis			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Abnormal loss of weight			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Breast milk substitute intolerance			
subjects affected / exposed	0 / 3557 (0.00%)	6 / 1741 (0.34%)	4 / 3494 (0.11%)
occurrences (all)	0	6	4
Cachexia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Dairy intolerance			
subjects affected / exposed	0 / 3557 (0.00%)	5 / 1741 (0.29%)	3 / 3494 (0.09%)
occurrences (all)	0	5	3
Decreased appetite			

subjects affected / exposed	2 / 3557 (0.06%)	3 / 1741 (0.17%)	2 / 3494 (0.06%)
occurrences (all)	2	3	2
Dehydration			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	5 / 3494 (0.14%)
occurrences (all)	1	0	5
Failure to thrive			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	4 / 3494 (0.11%)
occurrences (all)	0	1	4
Fluid retention			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Food intolerance			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Hypocalcaemia			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	1 / 3557 (0.03%)	10 / 1741 (0.57%)	17 / 3494 (0.49%)
occurrences (all)	1	10	17
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 3557 (0.00%)	4 / 1741 (0.23%)	3 / 3494 (0.09%)
occurrences (all)	0	4	3
Hypokalaemia			
subjects affected / exposed	2 / 3557 (0.06%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	2	1	0
Iron deficiency			
subjects affected / exposed	9 / 3557 (0.25%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	9	0	1
Lactose intolerance			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	2 / 3494 (0.06%)
occurrences (all)	0	2	2
Malnutrition			

subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	3 / 3494 (0.09%)
occurrences (all)	0	1	3
Metabolic acidosis			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Metabolic disorder			
subjects affected / exposed	0 / 3557 (0.00%)	1 / 1741 (0.06%)	0 / 3494 (0.00%)
occurrences (all)	0	1	0
Milk soy protein intolerance			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Obesity			
subjects affected / exposed	1 / 3557 (0.03%)	1 / 1741 (0.06%)	1 / 3494 (0.03%)
occurrences (all)	1	1	1
Overweight			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	6 / 3494 (0.17%)
occurrences (all)	0	3	6
Poor feeding infant			
subjects affected / exposed	0 / 3557 (0.00%)	3 / 1741 (0.17%)	12 / 3494 (0.34%)
occurrences (all)	0	4	13
Underweight			
subjects affected / exposed	1 / 3557 (0.03%)	6 / 1741 (0.34%)	3 / 3494 (0.09%)
occurrences (all)	1	6	3
Vitamin B12 deficiency			
subjects affected / exposed	2 / 3557 (0.06%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	2	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	1	0	1
Vitamin K deficiency			
subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	1 / 3494 (0.03%)
occurrences (all)	0	0	1
Weight gain poor			
subjects affected / exposed	0 / 3557 (0.00%)	2 / 1741 (0.11%)	7 / 3494 (0.20%)
occurrences (all)	0	2	7
Diabetes mellitus			

subjects affected / exposed	0 / 3557 (0.00%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 3557 (0.03%)	0 / 1741 (0.00%)	0 / 3494 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Placebo Group - Mother		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1175 / 1771 (66.35%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Anogenital warts			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Haemangioma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Haemangioma of skin			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Infantile haemangioma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Lipoma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Melanocytic naevus			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Ocular neoplasm			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Pyogenic granuloma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Skin papilloma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Ulcerated haemangioma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Xanthogranuloma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Uterine leiomyoma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Angiopathy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Cyanosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	11 / 1771 (0.62%)		
occurrences (all)	11		
Hypotension			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences (all)	3		

Varicose vein			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Vasodilatation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Blood pressure fluctuation			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Essential hypertension			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Haemorrhage			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hypertensive crisis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Inferior vena cava syndrome			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Raynaud's phenomenon			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Superficial vein thrombosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Thrombosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Surgical and medical procedures			
Medically induced preterm birth			
subjects affected / exposed	4 / 1771 (0.23%)		
occurrences (all)	4		
Episiotomy			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Birth trauma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Breech presentation			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences (all)	3		
Caput succedaneum			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Cephalhaematoma			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Cephalo-pelvic disproportion			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences (all)	2		
Complication of delivery			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Complication of pregnancy			
subjects affected / exposed	6 / 1771 (0.34%)		
occurrences (all)	6		
False labour			
subjects affected / exposed	4 / 1771 (0.23%)		
occurrences (all)	4		
Foetal acidosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Foetal distress syndrome			
subjects affected / exposed	6 / 1771 (0.34%)		
occurrences (all)	7		
Foetal growth restriction			

subjects affected / exposed	15 / 1771 (0.85%)			
occurrences (all)	15			
Foetal hypokinesia				
subjects affected / exposed	7 / 1771 (0.40%)			
occurrences (all)	7			
Foetal macrosomia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Foetal malpresentation				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Gestational diabetes				
subjects affected / exposed	18 / 1771 (1.02%)			
occurrences (all)	18			
Gestational hypertension				
subjects affected / exposed	20 / 1771 (1.13%)			
occurrences (all)	20			
Haemorrhage in pregnancy				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Hypothermia neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Jaundice neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Large for dates baby				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Low birth weight baby				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Meconium in amniotic fluid				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Meconium stain				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Morning sickness				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Neonatal disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Oligohydramnios				
subjects affected / exposed	10 / 1771 (0.56%)			
occurrences (all)	10			
Placenta praevia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Placental disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Polyhydramnios				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Poor weight gain neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Postpartum haemorrhage				
subjects affected / exposed	22 / 1771 (1.24%)			
occurrences (all)	22			
Pre-eclampsia				
subjects affected / exposed	11 / 1771 (0.62%)			
occurrences (all)	11			
Premature baby				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Premature labour				
subjects affected / exposed	43 / 1771 (2.43%)			
occurrences (all)	43			
Premature rupture of membranes				

subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Preterm premature rupture of membranes				
subjects affected / exposed	6 / 1771 (0.34%)			
occurrences (all)	6			
Prolonged labour				
subjects affected / exposed	6 / 1771 (0.34%)			
occurrences (all)	6			
Retained placenta or membranes				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Shoulder dystocia				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Small for dates baby				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Threatened labour				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Umbilical cord abnormality				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Umbilical cord around neck				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Umbilical cord haemorrhage				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Umbilical granuloma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Uterine contractions during pregnancy				

subjects affected / exposed	10 / 1771 (0.56%)			
occurrences (all)	11			
Uterine hypotonus				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Uterine irritability				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Weight decrease neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Abnormal cord insertion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Abnormal labour				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Afterbirth pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Amniorrhexis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Amniorrhoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Arrested labour				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Face presentation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Failed induction of labour				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Foetal damage				

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Foetal dystocia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Hyperemesis gravidarum				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Intrapartum haemorrhage				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Labour complication				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Labour pain				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Meconium abnormal				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Obstructed labour				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Placental calcification				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Placental polyp				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Postpartum uterine subinvolution				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Precipitate labour				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Premature separation of placenta				

subjects affected / exposed	2 / 1771 (0.11%)		
occurrences (all)	2		
Prolonged pregnancy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Prolonged rupture of membranes			
subjects affected / exposed	4 / 1771 (0.23%)		
occurrences (all)	4		
Retained products of conception			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Subchorionic haemorrhage			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Transverse presentation			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Umbilical cord compression			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Uterine atony			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences (all)	3		
Uterine hypertonus			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Uterine inversion			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Adverse food reaction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Administration site swelling			

subjects affected / exposed	8 / 1771 (0.45%)			
occurrences (all)	8			
Administration site pain				
subjects affected / exposed	231 / 1771 (13.04%)			
occurrences (all)	231			
Administration site erythema				
subjects affected / exposed	8 / 1771 (0.45%)			
occurrences (all)	8			
Asthenia				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Chills				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Crying				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cyst				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Developmental delay				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Discomfort				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	479 / 1771 (27.05%)			
occurrences (all)	480			
Feeling jittery				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fever neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

High-pitched crying				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hyperthermia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypertrophy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypothermia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ill-defined disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Illness				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Influenza like illness				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Injection site bruising				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Injection site erythema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Injection site oedema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Injection site pain				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Injection site pruritus				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			

Injection site swelling				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Irritability postvaccinal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Macrosomia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Malaise				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Oedema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Oedema peripheral				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Peripheral swelling				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Puncture site pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pyrexia				
subjects affected / exposed	15 / 1771 (0.85%)			
occurrences (all)	15			
Swelling				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Swelling face				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			

Thirst			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vaccination site induration			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vaccination site pain			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences (all)	2		
Vessel puncture site bruise			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vessel puncture site pain			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Scar inflammation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Immune system disorders			
ABO incompatibility			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Allergy to arthropod bite			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Allergy to arthropod sting			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Allergy to chemicals			

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Allergy to vaccine			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Alloimmunisation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Atopy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Drug hypersensitivity			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Food allergy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hypersensitivity			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Milk allergy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Multiple allergies			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Rhesus incompatibility			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Seasonal allergy			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Adnexa uteri cyst			

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Balanoposthitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bilateral breast buds				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Coital bleeding				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Genital blister				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Genital discomfort				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Genital labial adhesions				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Genital macule				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Genital ulceration				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Gynaecomastia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ovarian cyst				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pelvic pain				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Penile adhesion				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pruritus genital				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Scrotal swelling				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Testicular retraction				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vaginal discharge				
subjects affected / exposed	7 / 1771 (0.40%)			
occurrences (all)	8			
Vaginal disorder				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Vaginal haemorrhage				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Vulval oedema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vulvovaginal pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vulvovaginal pruritus				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Abnormal uterine bleeding				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Bartholin's cyst				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Breast engorgement				

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Breast inflammation				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	2			
Breast mass				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Breast pain				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Cystocele				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Endometrial hyperplasia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Female genital tract fistula				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Genital haemorrhage				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Heavy menstrual bleeding				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Intermenstrual bleeding				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Lactation disorder				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Lactation insufficiency				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Nipple disorder				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Perineal pain			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Shortened cervix			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Threatened uterine rupture			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Uterine haemorrhage			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Uterine prolapse			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Uterine scar			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Apnoea			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Apnoeic attack			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Asthmatic crisis			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Atelectasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bronchospasm				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bronchitis chronic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bronchiolitis obliterans syndrome				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Brief resolved unexplained event				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bronchial hyperreactivity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bronchial obstruction				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Catarrh				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Childhood asthma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Choking				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cough				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Dysphonia				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dyspnoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Epistaxis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hyperventilation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypoxia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Increased bronchial secretion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Infantile apnoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Lower respiratory tract congestion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Meconium aspiration syndrome				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nasal congestion				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Nasal discomfort				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nasal disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nasal dryness				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nasal inflammation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nasal obstruction				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Neonatal respiratory depression				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Neonatal respiratory distress				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Neonatal tachypnoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Pharyngeal erythema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pneumothorax				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Productive cough				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Pulmonary artery stenosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pulmonary congestion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pulmonary hypertension				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Respiration abnormal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Respiratory depression				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Respiratory disorder				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Respiratory distress				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Respiratory symptom				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rhinitis allergic				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Rhinorrhoea				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Rhonchi				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sinonasal obstruction				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sinus congestion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sneezing				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Stridor				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Tachypnoea			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Tracheomalacia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Upper respiratory tract congestion			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vasomotor rhinitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Immature respiratory system			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Nasal turbinate hypertrophy			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Nasal ulcer			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences (all)	3		

Brief psychotic disorder, with postpartum onset				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Initial insomnia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Insomnia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Irritability				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Panic attack				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Psychomotor retardation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Selective eating disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sleep disorder				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Tearfulness				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Depression				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Perinatal depression				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Postpartum anxiety				

subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Cholestasis of pregnancy			
subjects affected / exposed	4 / 1771 (0.23%)		
occurrences (all)	4		
Hyperbilirubinaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hypertransaminasaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Jaundice			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Biliary colic			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Cholecystitis chronic			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Investigations			
Acoustic stimulation tests abnormal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Apgar score low			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Audiogram abnormal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Blood alkaline phosphatase increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Blood bilirubin increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Blood glucose decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Blood glucose increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Blood iron decreased				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Blood potassium increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Blood pressure increased				
subjects affected / exposed	6 / 1771 (0.34%)			
occurrences (all)	6			
Breath sounds abnormal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Blood thyroid stimulating hormone abnormal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Body temperature increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

C-reactive protein increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cardiac murmur				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cardiac murmur functional				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Coombs direct test positive				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Coombs test positive				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Drug screen positive				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Electroencephalogram normal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
HIV test positive				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Haemoglobin decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Head circumference abnormal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Heart rate increased				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Human rhinovirus test positive				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Immunoreactive trypsinogen increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Influenza A virus test positive				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Medical observation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Otoacoustic emissions test abnormal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Oxygen saturation decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Platelet count decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Serum ferritin decreased				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Vitamin B12 decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Weight decreased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Weight increased				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
White blood cell count increased				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Foetal heart rate abnormal				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Foetal heart rate increased			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Foetal heart rate indeterminate			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Foetal monitoring			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Foetal monitoring abnormal			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Foetal non-stress test abnormal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Inhibin A increased			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Kleihauer-Betke test positive			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Streptococcus test positive			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Accidental exposure to product packaging			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Anal injury			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Arthropod bite			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Animal scratch				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Animal bite				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bone fissure				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Burns first degree				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Chemical burn				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Clavicle fracture				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Contusion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Craniocerebral injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eye injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Face injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fall				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Femur fracture				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Foreign body ingestion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fracture of clavicle due to birth trauma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Head injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Humerus fracture				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Immunisation reaction				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Incision site rash				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Joint dislocation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Joint injury				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Ligament sprain				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Limb injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Lip injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Mouth injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Muscle strain				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Nasal injury				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Perineal injury				
subjects affected / exposed	37 / 1771 (2.09%)			
occurrences (all)	37			
Post vaccination fever				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Procedural complication				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Radial head dislocation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Road traffic accident				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Scar				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin abrasion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Skin laceration				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Skin wound				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Soft tissue injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Thermal burn				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ulnar nerve injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Abdominal injury				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Anaemia postoperative				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Arthropod sting				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Foot fracture				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Incision site dermatitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Incision site haemorrhage				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Incision site pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Post procedural complication subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Post procedural fever subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Post procedural haemorrhage subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Postoperative wound complication subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Procedural headache subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Seroma subjects affected / exposed occurrences (all)	2 / 1771 (0.11%) 2		
Tooth fracture subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Urethral injury subjects affected / exposed occurrences (all)	3 / 1771 (0.17%) 3		
Uterine cervical laceration subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Vulvovaginal injury subjects affected / exposed occurrences (all)	18 / 1771 (1.02%) 18		
Wound dehiscence subjects affected / exposed occurrences (all)	1 / 1771 (0.06%) 1		
Congenital, familial and genetic disorders			

Accessory auricle				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Albinism				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Anorectal malformation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Anomaly of external ear congenital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ankyloglossia congenital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Atrial septal defect				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Birth mark				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Carnitine-acylcarnitine translocase deficiency				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cleft uvula				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital hypothyroidism				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital melanosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital musculoskeletal disorder of skull				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital naevus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital skin dimples				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital syphilis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital thymus absence				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Congenital umbilical hernia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Craniosynostosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cryptorchism				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cystic fibrosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dacryostenosis congenital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dermoid cyst				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ear malformation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fibromatosis colli of infancy				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Glucose-6-phosphate dehydrogenase deficiency				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Haemangioma congenital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Heart disease congenital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hydrocele				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Labial tie				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Laryngomalacia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Low set ears				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Lymphatic malformation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Naevus flammeus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Patent ductus arteriosus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Phimosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Polydactyly			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Preauricular cyst			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Pulmonary artery stenosis congenital			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Sickle cell anaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Sickle cell disease			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Stahl's ear			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Thalassaemia alpha			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Ventricular septal defect			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Congenital hydronephrosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Congenital renal cyst			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Bradycardia neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Bradycardia foetal			

subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Bradycardia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Extrasystoles				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Foetal arrhythmia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Foetal heart rate deceleration abnormality				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Left ventricular dilatation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Mitral valve incompetence				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Neonatal tachycardia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Palpitations				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Tachycardia				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Tachycardia foetal				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Ventricular hypertrophy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Nonreassuring foetal heart rate pattern			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Sinus tachycardia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Agitation neonatal			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Brain oedema			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Burning sensation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Carpal tunnel syndrome			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences (all)	2		
Cerebral haemorrhage			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences (all)	2		
Drooling			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Facial paralysis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Febrile convulsion			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fontanelle depressed				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gross motor delay				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Haemorrhage intracranial				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Headache				
subjects affected / exposed	452 / 1771 (25.52%)			
occurrences (all)	465			
Hypertonia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypotonia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
IVth nerve paralysis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Infant irritability				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Language disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Lethargy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Migraine				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Motor developmental delay				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Movement disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Myoclonus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nerve compression				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Neurodevelopmental delay				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nystagmus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Paraesthesia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Presyncope				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sciatica				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Seizure				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Seizure like phenomena				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Subependymal cyst				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Syncope subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Tethered cord syndrome subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Tremor neonatal subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Hypoaesthesia subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Lumbar radiculopathy subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Neuralgia subjects affected / exposed occurrences (all)	1 / 1771 (0.06%) 1		
Restless legs syndrome subjects affected / exposed occurrences (all)	1 / 1771 (0.06%) 1		
Sensory loss subjects affected / exposed occurrences (all)	1 / 1771 (0.06%) 1		
Tension headache subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Blood and lymphatic system disorders Anaemia of pregnancy subjects affected / exposed occurrences (all)	5 / 1771 (0.28%) 5		
Anaemia neonatal subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Anaemia			

subjects affected / exposed	24 / 1771 (1.36%)			
occurrences (all)	24			
Bandaemia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Haemorrhagic disease of newborn				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypochromic anaemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Iron deficiency anaemia				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Leukopenia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Lymph node pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Lymphadenopathy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Microcytic anaemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Neutropenia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Polycythaemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Thrombocytopenia				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Thrombocytopenia neonatal				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Blood loss anaemia			
subjects affected / exposed	5 / 1771 (0.28%)		
occurrences (all)	5		
Coagulopathy			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Normochromic normocytic anaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Normocytic anaemia			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Ear pain			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Eustachian tube dysfunction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Excessive cerumen production			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Middle ear inflammation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Otorrhoea			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		

Tympanic membrane disorder subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Tympanic membrane hyperaemia subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Vertigo subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Tinnitus subjects affected / exposed occurrences (all)	1 / 1771 (0.06%) 1			
Eye disorders Amblyopia subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Blepharitis subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Chalazion subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Conjunctival hyperaemia subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Corneal erosion subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Dacryostenosis acquired				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dry eye				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eye discharge				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eye inflammation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eye swelling				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eyelid ptosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Orbital oedema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Periorbital oedema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Strabismus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Swelling of eyelid				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Trichiasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vision blurred				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eczema eyelids				

subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Visual impairment			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences (all)	3		
Abdominal pain upper			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences (all)	3		
Abdominal pain lower			
subjects affected / exposed	7 / 1771 (0.40%)		
occurrences (all)	8		
Abdominal pain			
subjects affected / exposed	235 / 1771 (13.27%)		
occurrences (all)	241		
Abdominal hernia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Allergic colitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Anal rash			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Anal fissure			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Anal erythema			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Anal eczema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Aphthous ulcer				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Colitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Constipation				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Constipation neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Diarrhoea				
subjects affected / exposed	187 / 1771 (10.56%)			
occurrences (all)	187			
Diarrhoea haemorrhagic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dyschezia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dyspepsia				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	6			
Dysphagia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Enlarged uvula				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Enteritis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Enterocolitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eosinophilic colitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Flatulence				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Food poisoning				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Frequent bowel movements				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gastritis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Gastrointestinal disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	12 / 1771 (0.68%)			
occurrences (all)	12			
Gastrooesophageal reflux in neonate				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gingival cyst				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Haematemesis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			

Haematochezia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Haemorrhoids				
subjects affected / exposed	8 / 1771 (0.45%)			
occurrences (all)	9			
Haemorrhoids thrombosed				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hyperchlorhydria				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Infantile colic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Infantile spitting up				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Inguinal hernia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Meconium plug syndrome				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Mouth ulceration				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Nausea				
subjects affected / exposed	307 / 1771 (17.33%)			
occurrences (all)	313			
Oesophagitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Oral disorder				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Peptic ulcer				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Proctitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rectal prolapse				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Regurgitation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Stomatitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Teething				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tooth demineralisation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tooth development disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Toothache				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Umbilical hernia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vomiting				
subjects affected / exposed	153 / 1771 (8.64%)			
occurrences (all)	153			
Vomiting projectile				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Anal incontinence			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Ileus			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Odynophagia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Pelvic floor dysfunction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne infantile			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Alopecia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Blister			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Cafe au lait spots			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Cellulite			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Decubitus ulcer			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Dermal cyst			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		

Dermatitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dermatitis allergic				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Dermatitis atopic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dermatitis contact				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Dermatitis diaper				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Drug eruption				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dry skin				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eczema				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Eczema asteatotic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eczema infantile				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eczema nummular				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Erythema				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Erythema toxicum neonatorum				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hand dermatitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Herpes gestationis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hyperhidrosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ingrowing nail				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Intertrigo				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Macule				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Melanoderma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Milia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Miliaria				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nail fold inflammation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Papule				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Perioral dermatitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Petechiae				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pigmentation disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pityriasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pityriasis alba				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pityriasis rosea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Prurigo				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pruritus				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Rash				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rash erythematous				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rash macular				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rash maculo-papular				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Rash neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rash papular				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rash pruritic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Seborrhoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Seborrhoeic dermatitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin exfoliation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin hyperpigmentation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin hypopigmentation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin irritation				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin lesion				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin mass				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin ulcer				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Solar dermatitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Toxic skin eruption				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Transient neonatal pustular melanosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Umbilical discharge				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Urticaria				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Urticaria papular				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vitiligo				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Acne				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Excessive granulation tissue				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Polymorphic eruption of pregnancy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Prurigo of pregnancy				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Scar pain				

subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Skin reaction			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Anuria			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hydronephrosis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Oliguria			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	3 / 1771 (0.17%)		
occurrences (all)	3		
Proteinuria			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Pyelocaliectasis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Renal colic			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Urinary hesitation			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		

Vesicoureteric reflux subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Atonic urinary bladder subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Bladder spasm subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Urinary retention subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Precocious puberty subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Thyroid dysfunction in pregnancy subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Transient neonatal hyperthyrotropinaemia subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Musculoskeletal and connective tissue disorders Acquired plagiocephaly subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Arthralgia subjects affected / exposed occurrences (all)	2 / 1771 (0.11%) 2		
Asymmetric gluteal fold subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0		
Asymmetric thigh fold			

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Axillary mass				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Back pain				
subjects affected / exposed	11 / 1771 (0.62%)			
occurrences (all)	11			
Bone hypertrophy				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bone disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Foot deformity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Head deformity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypertonia neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypotonia neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Joint laxity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Joint noise				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ligament laxity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ligament pain				

subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Muscle spasms				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Muscle twitching				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Muscular weakness				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Musculoskeletal disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Newborn head moulding				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Nose deformity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pain in extremity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Posture abnormal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pubic pain				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Short stature				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Snapping hip syndrome			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Tendon disorder			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Torticollis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Coccydynia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Costochondritis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Plantar fasciitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	2 / 1771 (0.11%)		
occurrences (all)	2		
Abscess limb			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		

Abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Acute sinusitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Adenovirus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Adenoviral upper respiratory infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Anal candidiasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Anal abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Amoebic dysentery				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Amniotic cavity infection				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Ascariasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Balanitis candida				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Asymptomatic bacteriuria				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Bacterial disease carrier				

subjects affected / exposed	7 / 1771 (0.40%)			
occurrences (all)	7			
Bacterial vaginosis				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Bartholin's abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Beta haemolytic streptococcal infection				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Breast abscess				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Body tinea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Candida infection				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Candida nappy rash				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
COVID-19				
subjects affected / exposed	50 / 1771 (2.82%)			
occurrences (all)	50			
Bullous impetigo				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bronchitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Bronchiolitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Cellulitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	2			
Cellulitis orbital				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Conjunctivitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Conjunctivitis bacterial				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Conjunctivitis viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Croup infectious				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cystitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dacryocystitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dengue fever				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dermatitis infected				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Dermatophytosis of nail				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Diarrhoea infectious				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Dysentery				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Ear infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Ear infection viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eczema impetiginous				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eczema infected				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Enterobiasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Enterovirus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Erysipelas				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Erythema infectiosum				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Escherichia infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Escherichia urinary tract infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Exanthema subitum				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Eye infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eye infection staphylococcal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eye infection viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Eyelid infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Folliculitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fungal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Fungal skin infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Furuncle				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Gastroenteritis adenovirus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gastroenteritis bacterial				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Gastroenteritis viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gastrointestinal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gastrointestinal viral infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Genital candidiasis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Genital herpes				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Groin abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Groin infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hand-foot-and-mouth disease				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Herpangina				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Herpes simplex				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Herpes virus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Hordeolum				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Human herpesvirus 6 infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Impetigo				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Infected bite				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Klebsiella urinary tract infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Labyrinthitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Laryngotracheitis obstructive				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Localised infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Lower respiratory tract infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Lower respiratory tract infection viral subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Mastitis subjects affected / exposed occurrences (all)	15 / 1771 (0.85%) 17			
Metapneumovirus bronchiolitis subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Metapneumovirus infection subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Myringitis subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Nail bed infection subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Nasopharyngitis subjects affected / exposed occurrences (all)	19 / 1771 (1.07%) 20			
Neonatal infection subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Neonatal pneumonia subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Norovirus infection subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Omphalitis subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Ophthalmia neonatorum subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			

Oral candidiasis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Oral fungal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Oral viral infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Otitis externa fungal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Otitis media				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Otitis media acute				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Otitis media chronic				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Parainfluenzae virus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Parasitic gastroenteritis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Paronychia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			

Periodontitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pertussis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pharyngitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Pharyngitis streptococcal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pharyngotonsillitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Pneumonia bacterial				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pneumonia mycoplasmal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pneumonia viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pustule				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Pyoderma				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Respiratory syncytial virus bronchiolitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus bronchitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Respiratory syncytial virus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	18 / 1771 (1.02%)			
occurrences (all)	20			
Respiratory tract infection viral				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Rhinitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Rhinovirus infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Roseola				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Scarlet fever				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sepsis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sepsis neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Sinusitis				

subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Skin candida				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Skin infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Staphylococcal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Subcutaneous abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Subglottic laryngitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Suspected COVID-19				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Systemic viral infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Thyroglossal cyst infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tinea capitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tinea infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tinea pedis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tinea versicolour				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Toxoplasmosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tracheitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Tracheobronchitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Upper respiratory tract infection				
subjects affected / exposed	37 / 1771 (2.09%)			
occurrences (all)	43			
Upper respiratory tract infection bacterial				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Urinary tract infection				
subjects affected / exposed	49 / 1771 (2.77%)			
occurrences (all)	50			
Urogenital infection fungal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vaccination site abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vaginal infection				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Varicella				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			

Viral diarrhoea				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Viral pharyngitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Viral rash				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Viral rhinitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Viral tonsillitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Viral upper respiratory tract infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Vulvitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Vulvovaginal candidiasis				
subjects affected / exposed	9 / 1771 (0.51%)			
occurrences (all)	9			
Vulvovaginal mycotic infection				
subjects affected / exposed	5 / 1771 (0.28%)			
occurrences (all)	5			
Wound infection				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Bacterial vulvovaginitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			

Bacteriuria				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
COVID-19 pneumonia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Cervicitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Endometritis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Enterococcal infection				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Genital herpes simplex				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Genital infection female				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gingivitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Gonococcal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hepatitis B				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Kidney infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Mastitis postpartum				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			

Otosalpingitis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Perineal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Postoperative wound infection				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Puerperal infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Puerperal pyrexia				
subjects affected / exposed	3 / 1771 (0.17%)			
occurrences (all)	3			
Syphilis				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Tooth abscess				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Tooth infection				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Uterine infection				
subjects affected / exposed	2 / 1771 (0.11%)			
occurrences (all)	2			
Vulval abscess				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Vulvovaginitis				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Vulvovaginitis trichomonal				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			

Wound cellulitis subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Wound sepsis subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Metabolism and nutrition disorders Abnormal loss of weight subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Breast milk substitute intolerance subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Cachexia subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Dairy intolerance subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Decreased appetite subjects affected / exposed occurrences (all)	2 / 1771 (0.11%) 2			
Dehydration subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Failure to thrive subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Fluid retention subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Food intolerance subjects affected / exposed occurrences (all)	0 / 1771 (0.00%) 0			
Hyperglycaemia				

subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypoglycaemia				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypoglycaemia neonatal				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Hypokalaemia				
subjects affected / exposed	1 / 1771 (0.06%)			
occurrences (all)	1			
Iron deficiency				
subjects affected / exposed	4 / 1771 (0.23%)			
occurrences (all)	4			
Lactose intolerance				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Malnutrition				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Metabolic acidosis				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Metabolic disorder				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Milk soy protein intolerance				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Obesity				
subjects affected / exposed	0 / 1771 (0.00%)			
occurrences (all)	0			
Overweight				

subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Poor feeding infant			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Underweight			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vitamin B12 deficiency			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vitamin D deficiency			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Vitamin K deficiency			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Weight gain poor			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Diabetes mellitus			
subjects affected / exposed	1 / 1771 (0.06%)		
occurrences (all)	1		
Hyperlipidaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	0 / 1771 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 October 2020	The following points have been amended: Case definitions for lower respiratory tract illness have been modified to include the phrase “medically assessed." In addition, the success criteria for the primary objective on any RSV-associated lower respiratory tract infection has been changed. Previously the lower bound of this primary endpoint was 10%; it has been increased to 20%. The timing of interim analyses have been modified to make overall interim analyses operationally pragmatic. In addition, the corresponding study design operational characteristics have been updated.
23 June 2021	This protocol has been amended to: • implement the changes discussed and agreed with Center for Biologics Evaluation and Research (CBER). • extend the infant respiratory tract illness (RTI) surveillance to 12 months to ensure that this period will cover at least 1 full RSV season. • remove the collection of hematocrit samples due to challenges (mostly due to the COVID-19 pandemic) faced in several countries preventing the samples from reaching the central lab in adequate time for testing. • define an additional population for analysis: Modified Full Analysis - Efficacy Set.
10 February 2022	This protocol has been amended to: • change the trigger point for interim analyses which could lead to claim vaccine efficacy (2, 3 and 4) as there is a high chance of claiming vaccine efficacy (VE) earlier than initially anticipated. • add 2 new secondary descriptive efficacy objectives to assess VE against severe medically assessed LRTIs and any medically assessed LRTIs associated to RSV subtypes A and B separately in the infant participants from birth up to 6 months of age. • acquire further information on how the VE can be sustained up to 12 months post-birth. • remove the distribution of antibody titers/concentrations and the scatter plots showing the individual post-vaccination versus pre-vaccination results as well as scatter plots showing relationship between maternal and infants antibody titers. These analyses have already been described as part of previous completed RSV MAT studies and performing them in RSV MAT-009 (i.e. a larger sample size), is not expected to provide any additional critical information with regards to the study vaccine immunogenicity. • remove the section about predicted VE based on surrogate endpoint due to the limitation of data from internal epidemiological studies. Hence, the surrogate endpoint model cannot be robustly established and validated.
15 March 2022	Following a recommendation from the Independent Data Monitoring Committee of NCT04605159 (RSV MAT 009), GSK made the decision to stop enrolment and vaccination in the study. Ongoing study participants at that time continued to be monitored as part of the study. The Protocol was updated to reflect the change to study’s safety assessment plan.

23 February 2023	The following points have been amended: • The Benefit/Risk assessment has been updated to clarify the status of the safety signals after GSK's signal validation process. • The objectives and outcome measures section was updated. • RSV IgG antibody concentrations would be assessed only in maternal blood samples collected at delivery and cord blood* [*or an infant blood sample collected within 72 hours after birth (if no cord blood sample can be obtained)]. • RSV-B neutralizing antibody titers were removed from the secondary immunogenicity analysis. • Populations for analysis were updated to reflect the changes to the statistical analysis plan of the study, following the of decision to stop further enrolment and vaccination. • Country-specific requirements have been added for Spain and Argentina.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported