Clinical trial results:
A Phase IV, observer-blind, randomised, cross-over, placebo-controlled, multicentre study to assess the immunogenicity and safety of a single dose of Boostrix in pregnant women.

Summary

EudraCT number	2014-001119-38
Trial protocol	ES CZ FI IT
Global end of trial date	24 October 2017

Results information

Result version number	v1 (current)
This version publication date	30 August 2018
First version publication date	30 August 2018

Trial information

Trial identification

Sponsor protocol code	116945

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02377349
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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	24 October 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate that the maternally transferred antibodies against pertussis in the dTpa Group was superior to that in the Control Group in terms of geometric mean concentrations (GMCs) for the pertussis antibodies, in the cord blood sample.

Protection of trial subjects:

The subjects were observed closely for at least 30 minutes following the administration of the vaccine, with appropriate medical treatment readily available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 October 2015
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	Australia: 54
Country: Number of subjects enrolled	Canada: 159
Country: Number of subjects enrolled	Czech Republic: 75
Country: Number of subjects enrolled	Finland: 76
Country: Number of subjects enrolled	Italy: 15
Country: Number of subjects enrolled	Spain: 309
Worldwide total number of subjects	688
EEA total number of subjects	475

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	688
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 725 pregnant subjects were screened of which 690 were randomized to 2 groups. Of these, 2 subjects were withdrawn before vaccination. Therefore 688 subjects were enrolled: 1 subject was excluded from the statistical analysis, leaving 687 subjects that comprised the Total Vaccinated cohort.

Pre-assignment

Screening details:

Safety was assessed for infants born to vaccinated subjects as well as safety of dTap vaccination in the vaccinated pregnant subjects. There was also an assessment of the acceptance rate of a single dose of Boostrix among 723 eligible household contacts of the infants born to pregnant women enrolled in Spain, as part of an assessment of cocooning.

Period 1

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

Blinding implementation details:

Data was collected in an observer-blind manner: the vaccine recipient and those responsible for the evaluation of any study endpoints (e.g. safety, reactogenicity) were unaware of which vaccine was administered. The laboratory in charge of the laboratory testing was blinded to the treatment, and codes were used to link the subject and study (without any link to the treatment attributed to the subject) to each sample.

Arms

Are arms mutually exclusive?	Yes
Arm title	dTpa Group - Mother

Arm description:

This group consisted of pregnant women who received a single dose of Boostrix at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of the placebo post-delivery (within 72 hours).

Arm type	Experimental
Investigational medicinal product name	Boostrix
Investigational medicinal product code	
Other name	dTpa
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose was administered as intramuscular injection into the deltoid muscle of the non-dominant arm.

Investigational medicinal product name	Placebo for dTpa vaccine
Investigational medicinal product code	
Other name	NaCl
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose was administered as intramuscular injection into the deltoid muscle of the non-dominant arm.

Arm title	Control Group - Mother

Arm description:

This group consisted of pregnant women who received a single dose of placebo at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of Boostrix post-delivery (within 72 hours).

Arm type	Experimental
Investigational medicinal product name	Placebo for dTpa vaccine
Investigational medicinal product code	
Other name	NaCl
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose was administered as intramuscular injection into the deltoid muscle of the non-dominant arm.

Investigational medicinal product name	Boostrix
Investigational medicinal product code	
Other name	dTpa
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

One dose was administered as intramuscular injection into the deltoid muscle of the non-dominant arm.

Number of subjects in period 1[1]	dTpa Group - Mother	Control Group - Mother
Started	341	346
Completed	325	335
Not completed	16	11
Consent withdrawn by subject	5	3
Lost to follow-up (complete vaccination)	6	5
Unspecified	-	1
Lost to follow-up (partial vaccination)	1	-
Serious Adverse Event	1	-
Protocol deviation	3	2

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: Out of 688 subjects enrolled in this trial only 687 comprised the Total Vaccinated cohort, since one subject was excluded from the statistical analysis.

Baseline characteristics

Reporting groups	
Reporting group title	dTpa Group - Mother
Reporting group description:	
This group consisted of pregnant women who received a single dose of Boostrix at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of the placebo post-delivery (within 72 hours).	
Reporting group title	Control Group - Mother
Reporting group description:	
This group consisted of pregnant women who received a single dose of placebo at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of Boostrix post-delivery (within 72 hours).	

Reporting group values	dTpa Group - Mother	Control Group - Mother	Total
Number of subjects	341	346	687
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	32.7	32.5	
standard deviation	± 4.4	± 4.3	-
Gender categorical Units:			
Female	341	346	687
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
African Heritage / African American	3	9	12
American Indian or Alaskan Native	2	0	2
Asian - Central/South Asian Heritage	3	0	3
Asian - East Asian Heritage	4	1	5
Asian - Japanese Heritage	1	0	1
Asian - South East Asian Heritage	1	1	2
White - Arabic / North African Heritage	3	7	10
White - Caucasian / European Heritage	314	319	633
Unspecified	10	9	19

End points

End points reporting groups

Reporting group title	dTpa Group - Mother

Reporting group description:

This group consisted of pregnant women who received a single dose of Boostrix at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of the placebo post-delivery (within 72 hours).

Reporting group title	Control Group - Mother

Reporting group description:

This group consisted of pregnant women who received a single dose of placebo at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of Boostrix post-delivery (within 72 hours).

Subject analysis set title	dTpa Group - Infant
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group consisted of infants born to mothers (from dTpa Group Mother) who received a dose of Boostrix during pregnancy.

Subject analysis set title	Control Group - Infant
Subject analysis set type	Sub-group analysis

Subject analysis set description:

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

Subject analysis set title	Household Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

This group consisted of eligible household contacts of the infants born to pregnant women enrolled in Spain who received a single dose of Boostrix anytime during the study.

Primary: Antibody concentrations against pertussis toxoid antigen (anti-PT), filamentous haemagglutinin antigen (anti-FHA) and pertactin antigen (anti-PRN) in cord blood samples

End point title	Antibody concentrations against pertussis toxoid antigen (anti-PT), filamentous haemagglutinin antigen (anti-FHA) and pertactin antigen (anti-PRN) in cord blood samples

End point description:

Antibody concentrations were assessed by Enzyme-linked immunosorbent assay (ELISA), tabulated as Geometric Mean Concentrations (GMCs) and expressed in International units per mililiter (IU/mL) for the following assay cut-offs: 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA and 2.187 IU/mL for anti-PRN.

End point type	Primary

End point timeframe:

At delivery - Visit 3 (anytime after 28 weeks of gestation)

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	291	292		
Units: IU/mL				
geometric mean (confidence interval 95%)				

Anti-PT (N=290;292)	46.9 (41.2 to 53.3)	5.5 (4.8 to 6.3)		
Anti-FHA (N=291;292)	366.1 (329 to 407.3)	22.7 (19.7 to 26.2)		
Anti-PRN (N=290;291)	301.8 (250.9 to 362.9)	14.6 (12.1 to 17.7)		

Statistical analyses

Statistical analysis title	Statistical analysis 1

Statistical analysis description:

GMC ratio between groups (dTpa Group-Mother/Control Group-Mother) to demonstrate that maternally transferred antibodies against pertussis in the dTpa Group-Mother was superior to that in the Control Group-mother, in the cord blood sample at the time of delivery.

Comparison groups	Control Group - Mother v dTpa Group - Mother
Number of subjects included in analysis	583
Analysis specification	Pre-specified
Analysis type	superiority[1]
Method	2-sample t-test
Parameter estimate	GMC ratio
Point estimate	8.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.02
upper limit	10.2

Notes:

[1] - Criterion: The lower limit (LL) of the 95% confidence interval (CI) of the GMC ratio [dTpa Group-Mother/Control Group-Mother] for anti-PT antibodies was greater than or equal to (≥) 1.5.

Statistical analysis title	Statistical analysis 2

Statistical analysis description:

GMC ratio between groups (dTpa Group-Mother/Control Group-Mother) to demonstrate that maternally transferred antibodies against pertussis in the dTpa Group-Mother was superior to that in the Control Group-mother, in the cord blood sample at the time of delivery.

Comparison groups	Control Group - Mother v dTpa Group - Mother
Number of subjects included in analysis	583
Analysis specification	Pre-specified
Analysis type	superiority[2]
Method	2-sample t-test
Parameter estimate	GMC ratio
Point estimate	16.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.48
upper limit	19.24

Notes:

[2] - Criterion: The lower limit (LL) of the 95% confidence interval (CI) of the GMC ratio [dTpa Group-Mother/Control Group-Mother] for anti-FHA antibodies was greater than or equal to (≥) 1.5.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

GMC ratio between groups (dTpa Group-Mother/Control Group-Mother) to demonstrate that maternally transferred antibodies against pertussis in the dTpa Group-Mother was superior to that in the Control Group-mother, in the cord blood sample at the time of delivery.

Comparison groups	Control Group - Mother v dTpa Group - Mother
Number of subjects included in analysis	583
Analysis specification	Pre-specified
Analysis type	superiority[3]
Method	2-sample t-test
Parameter estimate	GMC ratio
Point estimate	20.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.86
upper limit	26.88

Notes:

[3] - Criterion: The lower limit (LL) of the 95% confidence interval (CI) of the GMC ratio [dTpa Group-Mother/Control Group-Mother] for anti-PRN antibodies was greater than or equal to (≥) 1.5.

Secondary: Percentage of subjects by pregnancy outcomes

End point title	Percentage of subjects by pregnancy outcomes

End point description:

Pregnancy outcomes included live birth with no congenital anomalies, live birth with congenital anomalies, still birth with no congenital anomalies, still birth with congenital anomalies, elective termination with no congenital anomalies and elective termination with congenital anomalies. No subjects with still birth or elective termination of infant were reported.

End point type	Secondary

End point timeframe:

From Day 0 (Visit 1) to Month 2 (Visit 4, end of the study).

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	346		
Units: Percentage of subjects				
number (confidence interval 95%)				
Live infant No apparent congenital anomaly	97.4 (95 to 98.8)	97.4 (95.1 to 98.8)		
Live infant congenital anomaly	2.6 (1.2 to 5)	2.3 (1 to 4.5)		
Lost to follow-up	0 (0 to 1.1)	0.3 (0 to 1.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with listed pregnancy/neonate related adverse events of interest

End point title	Percentage of subjects with listed pregnancy/neonate related

	adverse events of interest

End point description:

Listed pregnancy-related adverse events of interest/ neonate-related events of interest included gestational diabetes, pregnancy-related hypertension, premature rupture of mem-branes, preterm premature rupture of membranes, premature labour, premature uterine contractions, intrauterine growth restriction/poor foetal growth, pre-eclampsia, eclampsia, vaginal or intrauterine haemorrhage, maternal death, preterm birth, neonatal death, small for gestational age, neonatal hypoxic ischaemic encephalopathy and failure to thrive/growth deficiency were reported.

End point type	Secondary

End point timeframe:

From Day 0 (Visit 1) to Month 2 post-delivery (Visit 4, end of the study).

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	346		
Units: Percentage of subjects				
number (confidence interval 95%)				
Intrauterine growth restriction/poor foetal growth	1.5 (0.5 to 3.4)	0.6 (0.1 to 2.1)		
Pre-eclampsia	0.3 (0 to 1.6)	1.4 (0.5 to 3.3)		
Pregnancy-related hypertension	1.2 (0.3 to 3)	1.4 (0.5 to 3.3)		
Premature labour	3.8 (2 to 6.4)	3.2 (1.6 to 5.6)		
Premature rupture of membranes	3.8 (2 to 6.4)	4.3 (2.4 to 7)		
Premature uterine contractions	0.6 (0.1 to 2.1)	0.9 (0.2 to 2.5)		
Preterm birth	3.2 (1.6 to 5.7)	2.6 (1.2 to 4.9)		
Preterm premature rupture of membranes	1.2 (0.3 to 3)	2 (0.8 to 4.1)		
Small for gestational age	0.6 (0.1 to 2.1)	0.6 (0.1 to 2.1)		
Vaginal or intrauterine haemorrhage	2.6 (1.2 to 5)	2.9 (1.4 to 5.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of seroprotected subjects against Diphteria antigen (anti-D), Tetanus antigen (anti-T) and of seropositive subjects against anti-PT, anti-FHA and anti-PRN

End point title	Percentage of seroprotected subjects against Diphteria antigen (anti-D), Tetanus antigen (anti-T) and of seropositive subjects against anti-PT, anti-FHA and anti-PRN

End point description:

A seroprotected subject against diphteria and tetanus was a subject with antibody concentration ≥ 0.1 IU/mL. A seropositive subject was a subjects with antibody concentration ≥ 2.693 IU/mL for anti-PT, ≥ 2.046 IU/mL for anti-FHA and ≥ 2.187 IU/mL for anti-PRN.

End point type	Secondary

End point timeframe:

One month post vaccination (Day 30) during pregnancy

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	290	292		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-D (N=290;289)	97.6 (95.1 to 99)	70.6 (65 to 75.8)		
Anti-T (N=290;292)	100 (98.7 to 100)	96.6 (93.8 to 98.3)		
Anti-PT (N=289;292)	98.6 (96.5 to 99.6)	61.3 (55.5 to 66.9)		
Anti-FHA (N=290;291)	100 (98.7 to 100)	94.5 (91.2 to 96.8)		
Anti-PRN (N=290;291)	100 (98.7 to 100)	84.5 (79.9 to 88.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-D, anti-T, anti-PT, anti-FHA and anti-PRN antibody concentrations

End point title	Anti-D, anti-T, anti-PT, anti-FHA and anti-PRN antibody concentrations

End point description:

Antibody concentrations were determined by ELISA, tabulated as GMCs and expressed in IU/mL.

End point type	Secondary

End point timeframe:

One month post vaccination (Day 30) during pregnancy

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	290	292		
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D (N=290;289)	2.19 (1.87 to 2.57)	0.23 (0.19 to 0.27)		
Anti-T (N=290;292)	8.43 (7.72 to 9.2)	0.98 (0.86 to 1.11)		
Anti-PT (N=289;292)	45.6 (40.4 to 51.5)	4.1 (3.6 to 4.6)		
Anti-FHA (N=290;291)	317.5 (285 to 353.8)	15 (13.1 to 17.2)		
Anti-PRN (N=290;291)	283.6 (237.1 to 339.1)	10.5 (8.7 to 12.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with vaccine response to anti-D and anti-T

End point title	Percentage of subjects with vaccine response to anti-D and anti-T

End point description:

Vaccine response for anti-D and anti-T was defined as: for initially seronegative subjects (S-) with pre-vaccination concentration below cut-off: < 0.1 IU/mL) was an antibody concentration at least four times the assay cut-off (post-vaccination concentration ≥ 0.4 IU/mL); for initially seropositive subjects (S+) with pre-vaccination concentration ≥ 0.1 IU/mL): an increase in antibody concentrations of at least four times the pre-vaccination concentration.

End point type	Secondary

End point timeframe:

One month post vaccination (Day 30) during pregnancy

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	288	291		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-D, S- (N=103;83)	64.1 (54 to 73.3)	0 (0 to 4.3)		
Anti-D, S+ (N=184;205)	75 (68.1 to 81.1)	0 (0 to 1.8)		
Anti-D, Total (N=287;288)	71.1 (65.5 to 76.3)	0 (0 to 1.3)		
Anti-T, S- (N=12;10)	100 (73.5 to 100)	0 (0 to 30.8)		
Anti-T, S+ (N=276;281)	67.8 (61.9 to 73.2)	0 (0 to 1.3)		
Anti-T, Total (N=288;291)	69.1 (63.4 to 74.4)	0 (0 to 1.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with vaccine response to anti-PT, anti-FHA and anti-PRN

End point title	Percentage of subjects with vaccine response to anti-PT, anti-FHA and anti-PRN

End point description:

Vaccine response to PT, FHA and PRN antigens is defined as: for subjects with pre-vaccination antibody concentration below the assay cut-off (S-), post-vaccination anti-body concentration ≥ 4 times the assay cut-off; for subjects with pre-vaccination antibody concentration between the assay cut-off and below 4 times the assay cut-off (S+), post-vaccination antibody concentration ≥ 4 times the pre-vaccination antibody concentration, and for subjects with pre-vaccination antibody concentration ≥ 4 times the assay cut-off (S+), post-vaccination antibody concentration ≥2 times the pre-vaccination antibody concentration.

End point type	Secondary

End point timeframe:

One month post vaccination (Day 30) during pregnancy

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	288	291		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-PT, S- (N=121;107)	82.6 (74.7 to 88.9)	0.9 (0 to 5.1)		
Anti-PT, S+ (<4 cut-off) (N=108;117)	90.7 (83.6 to 95.5)	0 (0 to 3.1)		
Anti-PT, S+ (≥4 cut-off) (N=58;67)	93.1 (83.3 to 98.1)	3 (0.4 to 10.4)		
Anti-PT, Total (N=287;291)	87.8 (83.4 to 91.4)	1 (0.2 to 3)		
Anti-FHA, S- (N=16;16)	100 (79.4 to 100)	0 (0 to 20.6)		
Anti-FHA, S+ (<4 cut-off) (N=84;65)	100 (95.7 to 100)	0 (0 to 5.5)		
Anti-FHA, S+ (≥4 cut-off) (N=188;209)	89.9 (84.7 to 93.8)	1.9 (0.5 to 4.8)		
Anti-FHA, Total (N=288;290)	93.4 (89.9 to 96)	1.4 (0.4 to 3.5)		
Anti-PRN, S- (N=45;43)	86.7 (73.2 to 94.9)	0 (0 to 8.2)		
Anti-PRN, S+ (<4 cut-off) (N=98;86)	95.9 (89.9 to 98.9)	0 (0 to 4.2)		
Anti-PRN, S+ (≥4 cut-off) (N=145;161)	86.2 (79.5 to 91.4)	1.2 (0.2 to 4.4)		
Anti-PRN Total (N=288;290)	89.6 (85.5 to 92.9)	0.7 (0.1 to 2.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of seropositive subjects against anti-PT, anti-FHA and anti-PRN in the cord blood samples

End point title	Percentage of seropositive subjects against anti-PT, anti-FHA and anti-PRN in the cord blood samples

End point description:

For this assay the anti-PT, anti-FHA and anti-PRN seropositivity status was determined from the cord blood samples. The seropositivity cut-offs were the following: 2.693 IU/mL for anti-PT, 2.046 IU/mL for anti-FHA and 2.187 IU/mL for anti-PRN.

End point type	Secondary

End point timeframe:

At delivery - Visit 3 (anytime after 27 eligible weeks of gestation)

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	291	292		
Units: Percentage of subjects				
number (confidence interval 95%)				
Anti-PT (N=290;292)	98.6 (96.5 to 99.6)	68.8 (63.2 to 74.1)		
Anti-FHA (N=291;292)	100 (98.7 to 100)	96.6 (93.8 to 98.3)		
Anti-PRN (N=290;291)	99.7 (98.1 to 100)	88 (83.7 to 91.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with solicited local Adverse Events (AEs)

End point title	Percentage of subjects with solicited local Adverse Events (AEs)

End point description:

Assessed solicited local symptoms were pain, redness and swelling. “Any” = any report of the specified symptom irrespective of intensity grade. Dose 1 = pregnancy dose at Day 0 - Visit 1, Dose 2 = post-delivery dose at birth - Visit 3.

End point type	Secondary

End point timeframe:

During the 8-day (Day 0-Day 7) follow-up period after vaccination during pregnancy

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	335	343		
Units: Percentage of subjects				
number (confidence interval 95%)				
Any Pain, Dose 1 (N=335;343)	86.3 (82.1 to 89.8)	14.6 (11 to 18.8)		
Any Redness (mm), Dose 1 (N=335;343)	28.7 (23.9 to 33.8)	12.8 (9.5 to 16.8)		
Any Swelling (mm), Dose 1 (N=335;343)	25.1 (20.5 to 30.1)	3.5 (1.8 to 6)		

Any Pain, Dose 2 (N=324;330)	12.7 (9.2 to 16.8)	62.7 (57.3 to 68)		
Any Redness (mm), Dose 2 (N=324;330)	10.5 (7.4 to 14.4)	29.7 (24.8 to 34.9)		
Any Swelling (mm), Dose 2 (N=324;330)	5.2 (3.1 to 8.3)	26.4 (21.7 to 31.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with solicited general AEs

End point title	Percentage of subjects with solicited general AEs

End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal symptoms (nausea, vomiting, diarrhoea and/or abdominal pain), headache and fever [defined as oral,axillary or tympanic temperature ≥ 37.5 degrees Celsius (°C) or rectal temperature ≥ 38.0 °C]. "Any" = any report of the specified symptom irrespective of intensity grade. Dose 1 = pregnancy dose at Day 0 - Visit 1, Dose 2 = post-delivery dose at birth - Visit 3.

End point type	Secondary

End point timeframe:

During the 8-day (Day 0-Day 7) follow-up period after vaccination during pregnancy

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	335	342		
Units: Percentage of subjects				
number (confidence interval 95%)				
Any Fatigue, Dose 1 (N=335;342)	43.6 (38.2 to 49.1)	36.3 (31.2 to 41.6)		
Any Gastrointestinal symptom, Dose 1 (N=335;342)	17.9 (14 to 22.4)	15.2 (11.6 to 19.5)		
Any Headache, Dose 1 (N=335;342)	24.8 (20.2 to 29.8)	22.8 (18.5 to 27.6)		
Any Temperature/(Axillary) (°C), Dose 1(N=335;342)	1.2 (0.3 to 3)	0.9 (0.2 to 2.5)		
Any Fatigue, Dose 2 (N=324;331)	40.1 (34.7 to 45.7)	46.2 (40.8 to 51.8)		
Any Gastrointestinal symptom, Dose 2 (N=324;331)	9.9 (6.9 to 13.7)	12.7 (9.3 to 16.8)		
Any Headache, Dose 2 (N=324;331)	23.1 (18.7 to 28.1)	23.6 (19.1 to 28.5)		
Any Temperature/(Axillary) (°C), Dose 2(N=324;331)	4.6 (2.6 to 7.5)	9.1 (6.2 to 12.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with unsolicited AEs

End point title	Percentage of subjects with unsolicited AEs

End point description:

An unsolicited AE was any AE that was not solicited using a subject diary and that was spontaneously communicated by the subject. Also any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms was reported as an unsolicited adverse event. Dose 1 = pregnancy dose at Day 0 - Visit 1, Dose 2 = post-delivery dose at birth - Visit 3.

End point type	Secondary

End point timeframe:

Within 31 days (Day 0 – Day 30) after each vaccination

End point values	dTpa Group - Mother	Control Group - Mother		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	341	346		
Units: Percentage of subjects				
number (confidence interval 95%)				
Any unsolicited AE, Dose 1 (N=341;346)	38.7 (33.5 to 44.1)	35.5 (30.5 to 40.8)		
Any unsolicited AE, Dose 2 (N=336;342)	30.7 (25.8 to 35.9)	32.2 (27.2 to 37.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of infants with unsolicited AEs

End point title	Percentage of infants with unsolicited AEs

End point description:

An unsolicited AE was any AE that was not solicited using a subject diary and that was spontaneously communicated by the subject. Also any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms was reported as an unsolicited adverse event.

End point type	Secondary

End point timeframe:

From delivery to Month 2 (Visit 4, end of the study).

End point values	dTpa Group - Infant	Control Group - Infant		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	341	346		
Units: Percentage of subjects				
number (confidence interval 95%)				
Percentage of subjects	26.4 (21.8 to 31.4)	22.3 (18.0 to 27.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious AEs (SAEs)

End point title	Number of subjects with serious AEs (SAEs)

End point description:

A SAE was any untoward medical occurrence that resulted in death, was life threatening, required hospitalization or prolongation of hospitalization, resulted in disability/incapacity or a congenital anomaly/birth defect in the offspring of a study subject.

End point type	Secondary

End point timeframe:

From Day 0 (Visit 1) to Month 2 (Visit 4, end of the study).

End point values	dTpa Group - Mother	Control Group - Mother	dTpa Group - Infant	Control Group - Infant
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	341	346	341	346
Units: Participants				
Participants	51	52	52	45

End point values	Household Group			
Subject group type	Subject analysis set			
Number of subjects analysed	608			
Units: Participants				
Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of household contacts of the infants born to pregnant women vaccinated in Spain

End point title	Percentage of household contacts of the infants born to pregnant women vaccinated in Spain

End point description:

This analysis assessed the vaccination status of the household contacts (who accepted, received or refused vaccination) and also the reasons for refusal (not coming to site, refused to be vaccinated,

unspecified) as part of an assessment of cocooning among the eligible household contacts.

End point type	Secondary

End point timeframe:

From Day 0 (Visit 1) to Month 2 (Visit 4, end of the study).

End point values	Household Group			
Subject group type	Subject analysis set			
Number of subjects analysed	723			
Units: Percentage of household contacts				
number (confidence interval 95%)				
Accepted vaccination	84.4 (81.5 to 86.9)			
Received vaccination	84.1 (81.2 to 86.7)			
Refused vaccination	15.6 (13.1 to 18.5)			
Not coming to site	1.4 (0.7 to 2.5)			
Refused to be vaccinated	13.4 (11 to 16.1)			
Unspecified	0.8 (0.3 to 1.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of household contacts with SAEs

End point title	Percentage of household contacts with SAEs

End point description:

SAEs assessed include medical occurrences that results in death, are life threatening, require hospitalization or prolongation of hospitalization, results in disability/incapacity or are a congenital anomaly/birth defect in the offspring of a study subjects.

End point type	Secondary

End point timeframe:

During the 31-day (Days 0-30) follow-up period post-vaccination (Boostrix administered preferably 2 weeks before the birth of the infant, Visit 3).

End point values	Household Group			
Subject group type	Subject analysis set			
Number of subjects analysed	723			
Units: Percentage of subjects				
Percentage of subjects	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs: Days 0 - 7 following each dose; unsolicited AEs: Days 0 - 30 following each dose; SAEs: Day 0 - Month 2 (Mother Groups). Unsolicited AEs and SAEs: Day 0 - Month 2 (Infant Groups). SAEs: Days 0 - 30 post-vaccination (Household Group).

Adverse event reporting additional description:

No solicited symptoms were assessed for the Infants` Groups and Household Group.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	dTpa Group-Mother

Reporting group description:

This group consisted of pregnant women who received a single dose of Boostrix at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of the placebo post-delivery (within 72 hours).

Reporting group title	Control Group-Mother

Reporting group description:

This group consisted of pregnant women who received a single dose of placebo at 27-36 weeks (i.e. 27 weeks until 36 completed weeks) of gestation (Visit 1) and received a dose of Boostrix post-delivery (within 72 hours).

Reporting group title	Control Group-Infant

Reporting group description:

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

Reporting group title	Household Group

Reporting group description:

This group consisted of eligible household contacts of the infants born to pregnant women enrolled in Spain who received a single dose of Boostrix anytime during the study.

Reporting group title	dTpa Group - Infant

Reporting group description:

This group consisted of infants born to mothers (from dTpa Group Mother) who received a dose of Boostrix during pregnancy.

Serious adverse events	dTpa Group-Mother	Control Group-Mother	Control Group-Infant
Total subjects affected by serious adverse events			
subjects affected / exposed	51 / 341 (14.96%)	52 / 346 (15.03%)	45 / 346 (13.01%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pregnancy, puerperium and perinatal conditions			
Cephalhaematoma			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 distress syndrome			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (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
Foetal growth restriction			
subjects affected / exposed	3 / 341 (0.88%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	4 / 341 (1.17%)	4 / 346 (1.16%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hellp syndrome			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (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
Jaundice neonatal			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large for dates baby			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placenta praevia haemorrhage			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Polyhydramnios			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage			
subjects affected / exposed	5 / 341 (1.47%)	7 / 346 (2.02%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 7	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia			
subjects affected / exposed	1 / 341 (0.29%)	5 / 346 (1.45%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	9 / 346 (2.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 9
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature delivery			
subjects affected / exposed	4 / 341 (1.17%)	4 / 346 (1.16%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			
subjects affected / exposed	11 / 341 (3.23%)	11 / 346 (3.18%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 12	1 / 11	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes			
subjects affected / exposed	13 / 341 (3.81%)	17 / 346 (4.91%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 13	0 / 17	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes			
subjects affected / exposed	4 / 341 (1.17%)	5 / 346 (1.45%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained placenta or membranes			

subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small for dates baby			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	3 / 346 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Threatened labour			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	0 / 346 (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 contractions during pregnancy			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine atony			

subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
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 haemorrhage			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal haemorrhage			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asphyxia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 asphyxia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal respiratory depression			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 embolism			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
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 distress			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	4 / 346 (1.16%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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			
Fall			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural haemorrhage			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
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, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac septal defect			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cardiovascular anomaly			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital hydronephrosis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	3 / 346 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypospadias			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microtia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polydactyly			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pyloric stenosis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syndactyly			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transposition of the great vessels			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trisomy 21			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block complete			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Hypotonia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Somnolence neonatal			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia neonatal			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Isoimmune haemolytic disease			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
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			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 neonatal			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	6 / 346 (1.73%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash neonatal			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vesicoureteric reflux			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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			
Amniotic cavity infection			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (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
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Endometritis decidual			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	0 / 346 (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
Enterovirus infection			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 infection			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 infection			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
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			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis neonatal			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superinfection bacterial			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheitis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypocalcaemia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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 hypocalcaemia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
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	Household Group	dTpa Group - Infant	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 608 (0.00%)	52 / 341 (15.25%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal			

conditions			
Cephalhaematoma			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal distress syndrome			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal growth restriction			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gestational hypertension			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hellp syndrome			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice neonatal			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large for dates baby			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Placenta praevia haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polyhydramnios			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postpartum haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pre-eclampsia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature baby			
subjects affected / exposed	0 / 608 (0.00%)	11 / 341 (3.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature delivery			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature labour			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature rupture of membranes			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Preterm premature rupture of membranes			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained placenta or membranes			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small for dates baby			
subjects affected / exposed	0 / 608 (0.00%)	3 / 341 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Threatened labour			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Female genital tract fistula			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metrorrhagia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine atony			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Apnoea			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asphyxia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meconium aspiration syndrome			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal asphyxia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal respiratory depression			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			
subjects affected / exposed	0 / 608 (0.00%)	5 / 341 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Cardiac murmur			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac septal defect			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital cardiovascular anomaly			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital hydronephrosis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cryptorchism			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypospadias			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microtia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Polydactyly			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pyloric stenosis			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syndactyly			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transposition of the great vessels			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Trisomy 21			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular septal defect			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrioventricular block complete			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Hypotonia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Somnolence neonatal			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia neonatal			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Isoimmune haemolytic disease			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 608 (0.00%)	3 / 341 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia neonatal			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			

subjects affected / exposed	0 / 608 (0.00%)	8 / 341 (2.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash neonatal			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydronephrosis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vesicoureteric reflux			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Beta haemolytic streptococcal infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 608 (0.00%)	3 / 341 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Endometritis decidual			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterovirus infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal infection			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Perineal infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			

subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis neonatal			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superinfection bacterial			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypocalcaemia			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neonatal hypocalcaemia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	dTpa Group-Mother	Control Group-Mother	Control Group-Infant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	321 / 341 (94.13%)	303 / 346 (87.57%)	29 / 346 (8.38%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Melanocytic naevus			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Phlebitis			
subjects affected / exposed	1 / 341 (0.29%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	1	2	0
Raynaud's phenomenon			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Varicose vein			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Pregnancy, puerperium and perinatal conditions			
Afterbirth pain			
subjects affected / exposed	17 / 341 (4.99%)	20 / 346 (5.78%)	0 / 346 (0.00%)
occurrences (all)	17	20	0
Cephalhaematoma			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Cervical dilatation			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Labour pain			

subjects affected / exposed	2 / 341 (0.59%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	2	3	0
Oligohydramnios			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Small for dates baby			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Traumatic delivery			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Uterine contractions during pregnancy			
subjects affected / exposed	3 / 341 (0.88%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	3	1	0
Uterine hypotonus			
subjects affected / exposed	3 / 341 (0.88%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	3	2	0
Uterine irritability			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	2	0	0
Axillary pain			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	2	0	0
Chills			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Discomfort			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Fatigue			

subjects affected / exposed	188 / 341 (55.13%)	186 / 346 (53.76%)	0 / 346 (0.00%)
occurrences (all)	276	277	0
Granuloma			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Hypothermia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Impaired healing			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	3 / 341 (0.88%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	3	1	0
Injection site bruising			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	2	1	0
Injection site erythema			
subjects affected / exposed	106 / 341 (31.09%)	117 / 346 (33.82%)	0 / 346 (0.00%)
occurrences (all)	130	142	0
Injection site haematoma			
subjects affected / exposed	0 / 341 (0.00%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	0	3	0
Injection site induration			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Injection site mass			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	290 / 341 (85.04%)	223 / 346 (64.45%)	0 / 346 (0.00%)
occurrences (all)	330	258	0
Injection site pruritus			
subjects affected / exposed	4 / 341 (1.17%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	4	1	0
Injection site rash			

subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Injection site swelling			
subjects affected / exposed	91 / 341 (26.69%)	92 / 346 (26.59%)	0 / 346 (0.00%)
occurrences (all)	101	99	0
Injection site urticaria			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Nodule			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	20 / 341 (5.87%)	32 / 346 (9.25%)	0 / 346 (0.00%)
occurrences (all)	20	33	0
Swelling			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Vaccination site pain			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0

Seasonal allergy			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Breast engorgement			
subjects affected / exposed	2 / 341 (0.59%)	4 / 346 (1.16%)	0 / 346 (0.00%)
occurrences (all)	2	4	0
Breast inflammation			
subjects affected / exposed	2 / 341 (0.59%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	2	2	0
Breast mass			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Breast pain			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Cervical discharge			
subjects affected / exposed	1 / 341 (0.29%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	1	2	0
Menorrhagia			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Metrorrhagia			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Nipple disorder			
subjects affected / exposed	1 / 341 (0.29%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	1	1	0
Nipple inflammation			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Nipple pain			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Ovarian cyst torsion			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Perineal pain			
subjects affected / exposed	0 / 341 (0.00%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	0	3	0
Pruritus genital			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Suppressed lactation			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	2	1	0
Uterine pain			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Uterine prolapse			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Vaginal discharge			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Varicose veins vulval			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Vulvovaginal pain			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 341 (1.76%)	7 / 346 (2.02%)	0 / 346 (0.00%)
occurrences (all)	6	7	0
Epistaxis			

subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Grunting			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	3 / 341 (0.88%)	4 / 346 (1.16%)	0 / 346 (0.00%)
occurrences (all)	3	4	0
Nasal obstruction			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	13 / 341 (3.81%)	13 / 346 (3.76%)	0 / 346 (0.00%)
occurrences (all)	13	13	0
Respiratory distress			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 341 (0.00%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	0	3	0
Rhinorrhoea			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	2	0	0
Sinus congestion			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences (all)	0	0	2
Upper-airway cough syndrome			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			

Affect lability			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 341 (0.00%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	0	3	0
Irritability			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1
Investigations			
Blood pressure increased			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Heart rate decreased			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences (all)	0	0	2
Dislocation of vertebra			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Foreign body			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Incision site pain			
subjects affected / exposed	1 / 341 (0.29%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	1	1	0
Joint injury			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Laceration			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Post procedural haematoma			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	2	0	0
Post procedural inflammation			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Procedural haemorrhage			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Procedural headache			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	3 / 341 (0.88%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	3	2	0
Suture related complication			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Suture rupture			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	2	0	0
Wound dehiscence			
subjects affected / exposed	1 / 341 (0.29%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	1	3	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1

Nervous system disorders			
Aphonia			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	7 / 341 (2.05%)	4 / 346 (1.16%)	0 / 346 (0.00%)
occurrences (all)	8	4	0
Extrapyramidal disorder			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	129 / 341 (37.83%)	126 / 346 (36.42%)	0 / 346 (0.00%)
occurrences (all)	169	169	0
Migraine			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Migraine with aura			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	1 / 341 (0.29%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	1	1	0
Paralysis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	1 / 341 (0.29%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	1	3	0
Somnolence			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	2	0	0
Syncope			

subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 341 (3.23%)	14 / 346 (4.05%)	0 / 346 (0.00%)
occurrences (all)	11	14	0
Anaemia of pregnancy			
subjects affected / exposed	3 / 341 (0.88%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	3	3	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Ear pain			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Dacryostenosis acquired			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Eczema eyelids			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	3 / 341 (0.88%)	1 / 346 (0.29%)	1 / 346 (0.29%)
occurrences (all)	3	1	1
Abdominal pain			
subjects affected / exposed	4 / 341 (1.17%)	1 / 346 (0.29%)	6 / 346 (1.73%)
occurrences (all)	5	1	6
Abdominal pain lower			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			

subjects affected / exposed	1 / 341 (0.29%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	8 / 341 (2.35%)	10 / 346 (2.89%)	1 / 346 (0.29%)
occurrences (all)	8	10	1
Diarrhoea			
subjects affected / exposed	3 / 341 (0.88%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	3	0	0
Dyspepsia			
subjects affected / exposed	4 / 341 (1.17%)	4 / 346 (1.16%)	0 / 346 (0.00%)
occurrences (all)	4	5	0
Flatulence			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	78 / 341 (22.87%)	83 / 346 (23.99%)	0 / 346 (0.00%)
occurrences (all)	92	95	0
Gastrooesophageal reflux disease			
subjects affected / exposed	7 / 341 (2.05%)	6 / 346 (1.73%)	0 / 346 (0.00%)
occurrences (all)	7	6	0
Haemorrhoids			
subjects affected / exposed	4 / 341 (1.17%)	7 / 346 (2.02%)	0 / 346 (0.00%)
occurrences (all)	4	7	0
Inguinal hernia			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	2	0	0
Umbilical hernia			

subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	2	1	0
Hepatobiliary disorders			
Cholestasis of pregnancy			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences (all)	0	0	2
Jaundice			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	5 / 346 (1.45%)
occurrences (all)	0	0	5
Skin and subcutaneous tissue disorders			
Alopecia areata			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	1 / 341 (0.29%)	2 / 346 (0.58%)	1 / 346 (0.29%)
occurrences (all)	1	2	1
Dermatitis contact			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	1 / 346 (0.29%)
occurrences (all)	2	1	1
Hyperhidrosis			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Ingrowing nail			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences (all)	0	0	2
Night sweats			

subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Pruritus generalised			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	1 / 341 (0.29%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	1	1	0
Urticaria			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	2	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Pyelocaliectasis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Renal colic			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Urethral prolapse			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Thyroid dysfunction in pregnancy			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	3 / 341 (0.88%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	3	1	0
Back pain			
subjects affected / exposed	11 / 341 (3.23%)	13 / 346 (3.76%)	0 / 346 (0.00%)
occurrences (all)	11	14	0
Flank pain			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Ligament pain			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Limb discomfort			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Muscle haemorrhage			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	3 / 341 (0.88%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	3	3	0
Neck pain			
subjects affected / exposed	1 / 341 (0.29%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	1	3	0
Pain in extremity			
subjects affected / exposed	2 / 341 (0.59%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	2	3	0
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Bronchiolitis			

subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Conjunctivitis			
subjects affected / exposed	1 / 341 (0.29%)	3 / 346 (0.87%)	3 / 346 (0.87%)
occurrences (all)	1	3	3
Cystitis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Endometritis			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	2	1	0
Fungal skin infection			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	6 / 341 (1.76%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	6	1	0
Gastroenteritis viral			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Genital herpes			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Genital infection			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Genital infection fungal			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Groin abscess			

subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 341 (0.59%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	2	2	0
Mastitis			
subjects affected / exposed	10 / 341 (2.93%)	14 / 346 (4.05%)	0 / 346 (0.00%)
occurrences (all)	10	14	0
Mastitis postpartum			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	7 / 341 (2.05%)	12 / 346 (3.47%)	0 / 346 (0.00%)
occurrences (all)	7	12	0
Nipple infection			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	1 / 346 (0.29%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	1 / 341 (0.29%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	1	2	0
Otitis media acute			
subjects affected / exposed	0 / 341 (0.00%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	0	2	0
Periodontitis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			

subjects affected / exposed	2 / 341 (0.59%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	2	3	0
Pneumonia			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Postoperative abscess			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Postoperative wound infection			
subjects affected / exposed	2 / 341 (0.59%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	2	3	0
Pyelonephritis			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	2 / 341 (0.59%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	2	1	0
Respiratory tract infection viral			
subjects affected / exposed	2 / 341 (0.59%)	0 / 346 (0.00%)	2 / 346 (0.58%)
occurrences (all)	2	0	2
Rhinitis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	2 / 341 (0.59%)	3 / 346 (0.87%)	0 / 346 (0.00%)
occurrences (all)	2	3	0
Tinea pedis			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	11 / 341 (3.23%)	13 / 346 (3.76%)	1 / 346 (0.29%)
occurrences (all)	12	13	1
Urinary tract infection			
subjects affected / exposed	8 / 341 (2.35%)	10 / 346 (2.89%)	0 / 346 (0.00%)
occurrences (all)	8	11	0
Vaginal infection			

subjects affected / exposed	1 / 341 (0.29%)	2 / 346 (0.58%)	0 / 346 (0.00%)
occurrences (all)	1	2	0
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 341 (0.29%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	1	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Cow's milk intolerance			
subjects affected / exposed	0 / 341 (0.00%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 341 (0.00%)	1 / 346 (0.29%)	0 / 346 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	1 / 341 (0.29%)	0 / 346 (0.00%)	0 / 346 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Household Group	dTpa Group - Infant	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 608 (0.00%)	33 / 341 (9.68%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Melanocytic naevus			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Hypotension			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Phlebitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Raynaud's phenomenon			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Thrombosis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Varicose vein			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pregnancy, puerperium and perinatal conditions			
Afterbirth pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Cephalhaematoma			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Cervical dilatation			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Labour pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Oligohydramnios			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Small for dates baby			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Traumatic delivery			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Uterine contractions during pregnancy			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Uterine hypotonus			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Uterine irritability			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Axillary pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Discomfort			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Granuloma			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Hypothermia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Impaired healing			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site bruising			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site erythema			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site haematoma			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site induration			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site mass			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site pruritus			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site rash			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site swelling			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injection site urticaria			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Nodule			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Swelling			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vaccination site pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vessel puncture site bruise			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Milk allergy			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Seasonal allergy			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Breast engorgement			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Breast inflammation			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Breast mass			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Breast pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Cervical discharge			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Menorrhagia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Metrorrhagia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Nipple disorder			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Nipple inflammation			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Nipple pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Ovarian cyst torsion			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Pelvic pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Perineal pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pruritus genital			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Suppressed lactation			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Uterine pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Uterine prolapse			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vaginal discharge			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Varicose veins vulval			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Grunting			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Nasal obstruction			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Respiratory distress			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Rhinitis allergic			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Throat irritation			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Upper-airway cough syndrome			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Affect lability			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	

Irritability			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Investigations			
Blood pressure increased			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Heart rate decreased			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Dislocation of vertebra			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Foreign body			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Incision site pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Joint injury			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Laceration			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Post procedural haematoma			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Post procedural inflammation			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Procedural haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Procedural headache			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Suture related complication			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Suture rupture			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Wound dehiscence			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Supraventricular extrasystoles			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Aphonia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Extrapyramidal disorder			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Migraine			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Migraine with aura			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Paralysis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Restless legs syndrome			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Sciatica			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Anaemia of pregnancy			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Ear pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Dacryostenosis acquired			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences (all)	0	2	
Eczema eyelids			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	0 / 608 (0.00%)	9 / 341 (2.64%)	
occurrences (all)	0	9	
Abdominal pain lower			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Abdominal pain upper			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Gastritis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Inguinal hernia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Umbilical hernia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Cholestasis of pregnancy			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	

Hyperbilirubinaemia			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences (all)	0	2	
Jaundice			
subjects affected / exposed	0 / 608 (0.00%)	2 / 341 (0.59%)	
occurrences (all)	0	2	
Skin and subcutaneous tissue disorders			
Alopecia areata			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 608 (0.00%)	4 / 341 (1.17%)	
occurrences (all)	0	4	
Dermatitis contact			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Ingrowing nail			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Night sweats			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pruritus generalised			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Rash			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pyelocaliectasis			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Renal colic			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Urethral prolapse			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Thyroid dysfunction in pregnancy			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Flank pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Ligament pain			

subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Limb discomfort			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Muscle haemorrhage			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Amniotic cavity infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Bronchiolitis			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Bronchitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 608 (0.00%)	7 / 341 (2.05%)	
occurrences (all)	0	8	
Cystitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	

Endometritis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Fungal infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Gastroenteritis viral			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Genital herpes			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Genital infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Genital infection fungal			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Groin abscess			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Herpes simplex			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Hordeolum			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	

Mastitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Mastitis postpartum			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Nipple infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Oral herpes			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Otitis media acute			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Periodontitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Postoperative abscess			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Postoperative wound infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	

Pyelonephritis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection viral			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Rhinitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Tinea pedis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 608 (0.00%)	3 / 341 (0.88%)	
occurrences (all)	0	3	
Urinary tract infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vaginal infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Cow's milk intolerance			

subjects affected / exposed	0 / 608 (0.00%)	1 / 341 (0.29%)	
occurrences (all)	0	1	
Fluid retention			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	
Iron deficiency			
subjects affected / exposed	0 / 608 (0.00%)	0 / 341 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported