

**Clinical trial results:****Effect of folic acid supplementation in pregnancy on preeclampsia - Folic Acid Clinical Trial (FACT)**

A randomized, double-blind, placebo-controlled, Phase III, international multi-centre study of 4.0 mg of Folic Acid supplementation in pregnancy for the prevention of preeclampsia

Summary

EudraCT number	2012-001918-42
Trial protocol	GB
Global end of trial date	31 July 2016

Results information

Result version number	v1 (current)
This version publication date	26 June 2022
First version publication date	26 June 2022
Summary attachment (see zip file)	Effect of high dose folic acid supplementation in pregnancy on pre-eclampsia (FACT): double blind, phase III, randomised controlled, international, multicentre trial (Wen, 2018 BMJ. Effect of high dose folic acid on pre-eclampsia.pdf)

Trial information**Trial identification**

Sponsor protocol code	2009-107(Canadian)
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Additional study identifiers

ISRCTN number	ISRCTN23781770
ClinicalTrials.gov id (NCT number)	NCT01355159
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ottawa Hospital Research Institute
Sponsor organisation address	Civic Campus, 725 Parkdale Ave, Civic Box 675 Loeb Building, Ottawa, Canada, K1Y 4E9
Public contact	Marissa Akow, Ottawa Hospital Research Institute, 1 613-737-8899, makow@ohri.ca
Scientific contact	Marissa Akow, Ottawa Hospital Research Institute, 1 613-737-8899, makow@ohri.ca

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	11 July 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 July 2016
Global end of trial reached?	Yes
Global end of trial date	31 July 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To ascertain if a 4mg supplementation of Folic acid taken from early pregnancy until delivery prevents preeclampsia when compared with a placebo.

Protection of trial subjects:

4.0mg is standard recommended dose of folic acid in pregnancy complicated by hypertensive disorders.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 April 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 122
Country: Number of subjects enrolled	Canada: 1207
Country: Number of subjects enrolled	Australia: 310
Country: Number of subjects enrolled	Jamaica: 61
Country: Number of subjects enrolled	United Kingdom: 764
Worldwide total number of subjects	2464
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

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

Adults (18-64 years)	2464
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

1. Capability of subject to comprehend and comply with study requirements. 2. ≥ 18 years of age, 3. taking ≤ 1.1 mg folic acid daily, 4. live fetus, 5. gestational age between 8 and 16 weeks, 6. plan to deliver at participating hospital, 7. Experiencing a risk factor for preeclampsia (see Protocol).

Period 1

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

Blinding implementation details:

The data coordinating centre managed treatment allocation, and all participants, site investigators, coordinators and other research staff, and members of the trial coordinating centre were blinded to treatment allocation after randomisation. No unmasking occurred during the trial.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Group

Arm description:

Participant randomized into placebo group

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 x 1.0mg tablets once daily

Arm title	Experimental Group
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Arm description:

Subjects were randomized into the intervention/experimental group to receive 4.0mg of folic acid daily.

Arm type	Experimental
Investigational medicinal product name	Folic acid
Investigational medicinal product code	
Other name	Vitamin B9
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

4 x 1.0mg tablets once daily

Number of subjects in period 1^[1]	Placebo Group	Experimental Group
Started	1236	1227
Completed	1157	1144
Not completed	79	83
No primary outcome data	11	-
Consent withdrawn by subject	47	38
Adverse event, non-fatal	21	28
No primary data outcome	-	17

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: Of the participants allocated to the treatment group (n = 1228), one participant withdrew consent after randomization and were not included in the baseline characteristics analysis, therefore the final treatment sample size was n = 1227.

End points

End points reporting groups

Reporting group title	Placebo Group
Reporting group description:	
Participant randomized into placebo group	
Reporting group title	Experimental Group
Reporting group description:	
Subjects were randomized into the intervention/experimental group to receive 4.0mg of folic acid daily.	

Primary: Diagnosis of preeclampsia in current pregnancy

End point title	Diagnosis of preeclampsia in current pregnancy
End point description:	
End point type	Primary
End point timeframe:	
During current pregnancy	

End point values	Placebo Group	Experimental Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1236	1127		
Units: Diagnosis	21	30		

Statistical analyses

Statistical analysis title	Chi Squared
Statistical analysis description:	
Between the intervention and placebo group, chi squared, t-tests, and multiple log binomial regression was conducted on the primary outcome, and adjusting for confounders by parity, age, cigarette smoking, and other important prognostic factors identified a priori.	
Comparison groups	Experimental Group v Placebo Group
Number of subjects included in analysis	2363
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.05
Method	Chi-squared
Parameter estimate	Multiple log binomial regression
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.5
upper limit	2.5

<div>Variability estimate</div>	<div>Standard deviation</div>
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Adverse events

Adverse events information

Timeframe for reporting adverse events:

First administration of study treatment to last completed study visit

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	15
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Reporting groups

Reporting group title	active_mother
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Reporting group description: -

Reporting group title	active_infant
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Reporting group description:

Infants born to mothers in the active treatment group

Reporting group title	placebo_infant
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Reporting group description:

Infants born to mothers in the placebo group

Reporting group title	placebo_mother
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Reporting group description: -

Serious adverse events	active_mother	active_infant	placebo_infant
Total subjects affected by serious adverse events			
subjects affected / exposed	227 / 1227 (18.50%)	116 / 1364 (8.50%)	109 / 1374 (7.93%)
number of deaths (all causes)	1	19	24
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer	Additional description: Breast cancer		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma	Additional description: Squamous cell carcinoma		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine leiomyoma	Additional description: Uterine leiomyoma		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Blood pressure increased, Metabolic control	Additional description: Blood pressure increased, Metabolic control		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis	Additional description: Deep vein thrombosis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Gestational hypertension	Additional description: Gestational hypertension		
subjects affected / exposed	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 7	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage	Additional description: Haemorrhage		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Hypertension	Additional description: Hypertension		
subjects affected / exposed	20 / 1227 (1.63%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

Cervix cerclage procedure subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Cervix cerclage procedure		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Diabetes mellitus management subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Diabetes mellitus management		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Evacuation of retained products of conception subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Evacuation of retained products of conception		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Hospitalisation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Hospitalisation		
	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 2	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Steroid therapy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Steroid therapy		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions Abdominal pain, Vaginal haemorrhage subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Abdominal pain, Vaginal haemorrhage		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Abortion induced due to congenital anomaly subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Abortion induced due to congenital anomaly		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Abortion spontaneous	Additional description: Abortion spontaneous		

subjects affected / exposed	3 / 1227 (0.24%)	4 / 1364 (0.29%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 3	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 4	0 / 2
Death neonatal	Additional description: Death neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 1
Discordant twin	Additional description: Discordant twin		
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failed induction of labour	Additional description: Failed induction of labour		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
False labour	Additional description: False labour		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal death	Additional description: Foetal death		
subjects affected / exposed	4 / 1227 (0.33%)	6 / 1364 (0.44%)	10 / 1374 (0.73%)
occurrences causally related to treatment / all	0 / 4	0 / 6	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 6	0 / 8
Foetal growth restriction	Additional description: Foetal growth restriction		
subjects affected / exposed	1 / 1227 (0.08%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal hypokinesia	Additional description: Foetal hypokinesia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Gestational Diabetes	Additional description: Gestational diabetes		

subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage in pregnancy	Additional description: Haemorrhage in pregnancy		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
HELLP syndrome	Additional description: HELLP syndrome		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Hyperemesis gravidarum	Additional description: Hyperemesis gravidarum		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice neonatal	Additional description: Jaundice neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	8 / 1364 (0.59%)	7 / 1374 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 8	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligohydramnios	Additional description: Oligohydramnios		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
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	Additional description: Placenta praevia haemorrhage		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyhydramnios	Additional description: Polyhydramnios		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postpartum haemorrhage	Additional description: Postpartum haemorrhage		

subjects affected / exposed	15 / 1227 (1.22%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 15	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pre-eclampsia	Additional description: Pre-eclampsia		
subjects affected / exposed	16 / 1227 (1.30%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 16	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby	Additional description: Premature baby		
subjects affected / exposed	5 / 1227 (0.41%)	47 / 1364 (3.45%)	42 / 1374 (3.06%)
occurrences causally related to treatment / all	0 / 5	0 / 47	0 / 42
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 7
Premature labour	Additional description: Premature labour		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes	Additional description: Premature rupture of membranes		
subjects affected / exposed	11 / 1227 (0.90%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature rupture of membranes, Placental transfusion syndrome	Additional description: Premature rupture of membranes, Placental transfusion syndrome		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature separation of placenta	Additional description: Premature separation of placenta		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Preterm premature rupture of membranes	Additional description: Preterm premature rupture of membranes		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary congestion, Pre-eclampsia	Additional description: Pulmonary congestion, Pre-eclampsia		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Retained products of conception	Additional description: Retained products of conception		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Shortened cervix, Polyhydramnios	Additional description: Shortened cervix, Polyhydramnios		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shoulder dystocia	Additional description: Shoulder dystocia		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Small for dates baby	Additional description: Small for dates baby		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stillbirth	Additional description: Stillbirth		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 2
Threatened labour	Additional description: Threatened labour		
subjects affected / exposed	20 / 1227 (1.63%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 20	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical cord abnormality	Additional description: Umbilical cord abnormality		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine contractions abnormal	Additional description: Uterine contractions abnormal		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine contractions during pregnancy	Additional description: Uterine contractions during pregnancy		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasa praevia	Additional description: Vasa praevia		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decrease neonatal	Additional description: Weight decrease neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Abdominal pain, Pyrexia	Additional description: Abdominal pain, Pyrexia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased, Blood glucose	Additional description: Blood pressure increased, Blood glucose		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
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 pressure increased, Headache	Additional description: Blood pressure increased, Headache		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood pressure increased, Pulmonary edema	Additional description: Blood pressure increased, Pulmonary edema		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cholecystitis, Cholelithiasis, Pancreatitis	Additional description: Cholecystitis, Cholelithiasis, Pancreatitis		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis, HELLP	Additional description: Cholestasis, HELLP		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Chorioamnionitis, Sepsis	Additional description: Chorioamnionitis, Sepsis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Cyst	Additional description: Cyst		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration, Gastritis, Urinary tract infection	Additional description: Dehydration, Gastritis, Urinary tract infection		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Dysplasia	Additional description: Dysplasia		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elevated hepatic enzymes, Pre-eclampsia, Glucose intolerance, Placental transfusion syndrome	Additional description: Elevated hepatic enzymes, Pre-eclampsia, Glucose intolerance, Placental transfusion syndrome		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Headache, Amylase increased	Additional description: Headache, Amylase increased		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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

Headache, Hypertension, Vision blurred	Additional description: Headache, Hypertension, Vision blurred		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache, Pain in extremity	Additional description: Headache, Pain in extremity		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache, Oedema, Hypertension	Additional description: Headache, Oedema, Hypertension		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
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, Congenital cardiovascular anomaly	Additional description: Hypoglycaemia, Congenital cardiovascular anomaly		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia, Sepsis	Additional description: Hypoglycaemia, Sepsis		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large for dates baby, Transient tachypnoea, Septal hypertrophy, Patent Ductus Arteriosus	Additional description: Large for dates baby, Transient tachypnoea, Septal hypertrophy, Patent Ductus Arteriosus		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neonatal death due to Congenital cardiovascular anomaly, Pulmonary artery stenosis congenital	Additional description: Neonatal death due to Congenital cardiovascular anomaly, Pulmonary artery stenosis congenital		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Neonatal respiratory acidosis, Metabolic acidosis	Additional description: Neonatal respiratory acidosis, Metabolic acidosis		

subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby, Death neonatal	Additional description: Premature baby, Death neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby, Gastroschisis, Hyponatremia, Metabolic acidosis	Additional description: Premature baby, Gastroschisis, Hyponatremia, Metabolic acidosis		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature baby, Hypoglycemia, Desaturation	Additional description: Premature baby, Hypoglycemia, Desaturation		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature cervical change, Polyhydramnios	Additional description: Premature cervical change, Polyhydramnios		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism symptoms	Additional description: Pulmonary embolism symptoms		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia, Low hemoglobin, Viral infection	Additional description: Tachycardia, Low hemoglobin, Viral infection		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Threatened labour, Cystitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Threatened labour, Cystitis		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Unstable foetal lie, Polyhydramnios subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Unstable foetal lie, Polyhydramnios		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Weight loss, Hypernatraemia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Weight loss, Hypernatraemia		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
	0 / 0	0 / 1	0 / 1
	0 / 0	0 / 0	0 / 0
Immune system disorders Anaphylactic reaction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Anaphylactic reaction		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Milk allergy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Milk allergy		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
	0 / 0	0 / 1	0 / 1
	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders Cervical polyp subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Cervical polyp		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Scrotal mass subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Scrotal mass		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	0 / 0	0 / 0	0 / 1
	0 / 0	0 / 0	0 / 0
Shortened cervix subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Shortened cervix		
	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 2	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0

Vaginal haemorrhage subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Vaginal haemorrhage		
	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 7	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders Apnoea subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Apnoea		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
	0 / 0	0 / 0	0 / 2
	0 / 0	0 / 0	0 / 0
Asthma subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Asthma		
	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 2	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Dyspnoea subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Dyspnoea		
	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 2	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Hypoxia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Hypoxia		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	0 / 0	0 / 0	0 / 1
	0 / 0	0 / 0	0 / 0
Neonatal aspiration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Neonatal aspiration		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
	0 / 0	0 / 1	0 / 0
	0 / 0	0 / 0	0 / 0
Neonatal respiratory distress syndrome subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Neonatal respiratory distress syndrome		
	0 / 1227 (0.00%)	2 / 1364 (0.15%)	1 / 1374 (0.07%)
	0 / 0	0 / 2	0 / 1
	0 / 0	0 / 0	0 / 0
Pneumonia, Respiratory distress subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Pneumonia, Respiratory distress		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
	0 / 0	0 / 1	0 / 0
	0 / 0	0 / 0	0 / 0

Pneumonia aspiration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Pneumonia aspiration		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
	0 / 0	0 / 1	0 / 0
	0 / 0	0 / 0	0 / 0
Pneumothorax subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Pneumothorax		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
	0 / 0	0 / 1	0 / 0
	0 / 0	0 / 0	0 / 0
Pulmonary embolism subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Pulmonary embolism		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Pulmonary oedema subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Pulmonary oedema		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Psychiatric disorders Mental disorder subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Mental disorder		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Investigations Blood bilirubin increased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Blood bilirubin increased		
	0 / 1227 (0.00%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
	0 / 0	0 / 2	0 / 0
	0 / 0	0 / 0	0 / 0
Blood creatinine increased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Blood creatinine increased		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Blood glucose subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Blood glucose		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0

Blood glucose decreased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Blood glucose decreased		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Blood glucose increased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Blood glucose increased		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Blood pressure increased subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Blood pressure increased		
	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 7	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Blood pressure increased, Proteinuria subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Blood pressure increased, Proteinuria		
	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 2	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Cardiac murmur subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Cardiac murmur		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	0 / 0	0 / 0	0 / 1
	0 / 0	0 / 0	0 / 0
Foetal monitoring abnormal subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Foetal monitoring abnormal		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Foetal non-stress test abnormal subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Foetal non-stress test abnormal		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Glucose tolerance test abnormal subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Glucose tolerance test abnormal		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Ultrasound Doppler abnormal	Additional description: Ultrasound Doppler abnormal		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ultrasound scan abnormal	Additional description: Ultrasound scan abnormal		
subjects affected / exposed	1 / 1227 (0.08%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urine output decreased	Additional description: Urine output decreased		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Injury, poisoning and procedural complications			
Abdominal injury	Additional description: Abdominal injury		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning	Additional description: Alcohol poisoning		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brachial plexus injury	Additional description: Brachial plexus injury		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture	Additional description: Fracture		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound complication	Additional description: Postoperative wound complication		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence	Additional description: Wound dehiscence		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection	Additional description: Wound infection		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Ankyloglossia congenital	Additional description: Ankyloglossia congenital		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cleft lip and palate	Additional description: Cleft lip and palate		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital cardiovascular anomaly	Additional description: Congenital cardiovascular anomaly		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital ectopic bladder	Additional description: Congenital ectopic bladder		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital inguinal hernia	Additional description: Congenital inguinal hernia		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital laryngeal stridor	Additional description: Congenital laryngeal stridor		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytogenetic abnormality	Additional description: Cytogenetic abnormality		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Encephalocele	Additional description: Encephalocele		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Fallot's tetralogy	Additional description: Fallot's tetralogy		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucose-6-phosphate dehydrogenase deficiency	Additional description: Glucose-6-phosphate dehydrogenase deficiency		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Holoprosencephaly	Additional description: Holoprosencephaly		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Renal aplasia	Additional description: Renal aplasia		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Trisomy 13	Additional description: Trisomy 13		
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	0 / 1374 (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
Univentricular heart	Additional description: Univentricular heart		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular anomaly	Additional description: Vascular anomaly		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiac disorders			
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Cardiomyopathy	Additional description: Cardiomyopathy		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Palpitations	Additional description: Palpitations		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia foetal	Additional description: Tachycardia foetal		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia	Additional description: Ventricular tachycardia		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
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			
Cerebral haemorrhage	Additional description: Cerebral haemorrhage		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ventricle dilatation	Additional description: Cerebral ventricle dilatation		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache	Additional description: Headache		

subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy	Additional description: Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine	Additional description: Migraine		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine, Syncope, Bell's palsy	Additional description: Migraine, Syncope, Bell's palsy		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Partial seizures	Additional description: Partial seizures		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage	Additional description: Subarachnoid haemorrhage		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Haemolytic anaemia	Additional description: Haemolytic anaemia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Placental transfusion syndrome	Additional description: Placental transfusion syndrome		

subjects affected / exposed	2 / 1227 (0.16%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo	Additional description: Vertigo		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension	Additional description: Abdominal distension		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia	Additional description: Haematochezia		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction	Additional description: Intestinal obstruction		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Necrotising colitis	Additional description: Necrotising colitis		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis	Additional description: Pancreatitis		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage	Additional description: Upper gastrointestinal haemorrhage		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Volvulus	Additional description: Volvulus		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Acute fatty liver of pregnancy	Additional description: Acute fatty liver of pregnancy		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary colic	Additional description: Biliary colic		

subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis	Additional description: Cholestasis		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholestasis of pregnancy	Additional description: Cholestasis of pregnancy		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia neonatal	Additional description: Hyperbilirubinaemia neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-alcoholic steatohepatitis	Additional description: Non-alcoholic steatohepatitis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Eczema	Additional description: Eczema		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Nephrolithiasis	Additional description: Nephrolithiasis			
	subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic	Additional description: Renal colic			
	subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment	Additional description: Renal impairment			
	subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric obstruction	Additional description: Ureteric obstruction			
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary incontinence	Additional description: Urinary incontinence			
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention	Additional description: Urinary retention			
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders				
	Foot deformity	Additional description: Foot deformity		
	subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion	Additional description: Intervertebral disc protrusion			
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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

Myalgia	Additional description: Myalgia		
	subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Musculoskeletal pain	Additional description: Musculoskeletal pain		
	subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Pain in extremity	Additional description: Pain in extremity		
	subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)
	occurrences causally related to treatment / all	0 / 0	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Pubic pain	Additional description: Pubic pain		
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Infections and infestations			
	Additional description: Appendicitis		
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
Arthritis bacterial	Additional description: Arthritis bacterial		
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Bronchiolitis	Additional description: Bronchiolitis		
	subjects affected / exposed	1 / 1227 (0.08%)	2 / 1364 (0.15%)
	occurrences causally related to treatment / all	0 / 1	0 / 2
	deaths causally related to treatment / all	0 / 0	0 / 0
Bronchitis	Additional description: Bronchitis		
	subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0
	deaths causally related to treatment / all	0 / 0	0 / 0
Cellulitis	Additional description: Cellulitis		

subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Chorioamnionitis	Additional description: Chorioamnionitis		
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 0
Congenital pneumonia	Additional description: Congenital pneumonia		
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	0 / 1374 (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
Endometritis	Additional description: Endometritis		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Endometritis, Urinary tract infection	Additional description: Endometritis, Urinary tract infection		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral	Additional description: Gastroenteritis viral		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Impaired gastric emptying	Additional description: Impaired gastric emptying		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Infection, Endometritis, Left Mastitis, Urinary tract infection	Additional description: Infection, Endometritis, Left Mastitis, Urinary tract infection		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Influenza	Additional description: Influenza		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral	Additional description: Meningitis viral		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis	Additional description: Mastitis		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Moraxella infection	Additional description: Moraxella infection		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
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	Additional description: Pneumonia		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection	Additional description: Postoperative wound infection		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis	Additional description: Sepsis		

subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (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
Sepsis neonatal	Additional description: Sepsis neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	3 / 1374 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Streptococcal urinary tract infection	Additional description: Streptococcal urinary tract infection		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
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	Additional description: Upper respiratory tract infection		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	4 / 1227 (0.33%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection	Additional description: Viral infection		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Cow's milk intolerance, Gastroesophageal reflux disease	Additional description: Cow's milk intolerance, Gastroesophageal reflux disease		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 1227 (0.08%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus	Additional description: Diabetes mellitus		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Diabetes mellitus inadequate control	Additional description: Diabetes mellitus inadequate control		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis	Additional description: Diabetic ketoacidosis		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid overload	Additional description: Fluid overload		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Food intolerance	Additional description: Food intolerance		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	5 / 1227 (0.41%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	2 / 1227 (0.16%)	1 / 1364 (0.07%)	0 / 1374 (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
Ketosis	Additional description: Ketosis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Metabolic syndrome	Additional description: Metabolic syndrome		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (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
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	placebo_mother		
Total subjects affected by serious adverse events			
subjects affected / exposed	195 / 1236 (15.78%)		
number of deaths (all causes)	8		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer	Additional description: Breast cancer		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma	Additional description: Squamous cell carcinoma		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma	Additional description: Uterine leiomyoma		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Blood pressure increased, Metabolic control	Additional description: Blood pressure increased, Metabolic control		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis	Additional description: Deep vein thrombosis		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension	Additional description: Gestational hypertension		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Haemorrhage	Additional description: Haemorrhage		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension	Additional description: Hypertension		
subjects affected / exposed	16 / 1236 (1.29%)		
occurrences causally related to treatment / all	0 / 16		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis	Additional description: Hypertensive crisis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Varicose vein	Additional description: Varicose vein		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Cervix cerclage procedure	Additional description: Cervix cerclage procedure		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus management	Additional description: Diabetes mellitus management		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Evacuation of retained products of conception	Additional description: Evacuation of retained products of conception		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hospitalisation	Additional description: Hospitalisation		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Steroid therapy	Additional description: Steroid therapy		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abdominal pain, Vaginal haemorrhage	Additional description: Abdominal pain, Vaginal haemorrhage		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion induced due to congenital anomaly	Additional description: Abortion induced due to congenital anomaly		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abortion spontaneous	Additional description: Abortion spontaneous		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 2		
Death neonatal	Additional description: Death neonatal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Discordant twin	Additional description: Discordant twin		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Failed induction of labour subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Failed induction of labour		
	1 / 1236 (0.08%)		
	0 / 1		
False labour subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: False labour		
	0 / 1236 (0.00%)		
	0 / 0		
Foetal death subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Foetal death		
	11 / 1236 (0.89%)		
	0 / 11		
Foetal growth restriction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Foetal growth restriction		
	5 / 1236 (0.40%)		
	0 / 5		
Foetal hypokinesia subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Foetal hypokinesia		
	1 / 1236 (0.08%)		
	0 / 1		
Gestational Diabetes subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Gestational diabetes		
	2 / 1236 (0.16%)		
	0 / 2		
Haemorrhage in pregnancy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Haemorrhage in pregnancy		
	7 / 1236 (0.57%)		
	0 / 7		
HELLP syndrome subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: HELLP syndrome		
	1 / 1236 (0.08%)		
	0 / 1		
Hyperemesis gravidarum	Additional description: Hyperemesis gravidarum		
	0 / 0		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Jaundice neonatal	Additional description: Jaundice neonatal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oligohydramnios	Additional description: Oligohydramnios		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placenta praevia haemorrhage	Additional description: Placenta praevia haemorrhage		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyhydramnios	Additional description: Polyhydramnios		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postpartum haemorrhage	Additional description: Postpartum haemorrhage		
subjects affected / exposed	9 / 1236 (0.73%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Pre-eclampsia	Additional description: Pre-eclampsia		
subjects affected / exposed	11 / 1236 (0.89%)		
occurrences causally related to treatment / all	0 / 11		
deaths causally related to treatment / all	0 / 0		
Premature baby	Additional description: Premature baby		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Premature labour	Additional description: Premature labour		

subjects affected / exposed	6 / 1236 (0.49%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Premature rupture of membranes	Additional description: Premature rupture of membranes		
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Premature rupture of membranes, Placental transfusion syndrome	Additional description: Premature rupture of membranes, Placental transfusion syndrome		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature separation of placenta	Additional description: Premature separation of placenta		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Preterm premature rupture of membranes	Additional description: Preterm premature rupture of membranes		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary congestion, Pre-eclampsia	Additional description: Pulmonary congestion, Pre-eclampsia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retained products of conception	Additional description: Retained products of conception		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Shortened cervix, Polyhydramnios	Additional description: Shortened cervix, Polyhydramnios		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Shoulder dystocia	Additional description: Shoulder dystocia		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Small for dates baby	Additional description: Small for dates baby		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stillbirth	Additional description: Stillbirth		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Threatened labour	Additional description: Threatened labour		
subjects affected / exposed	18 / 1236 (1.46%)		
occurrences causally related to treatment / all	0 / 18		
deaths causally related to treatment / all	0 / 0		
Umbilical cord abnormality	Additional description: Umbilical cord abnormality		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine contractions abnormal	Additional description: Uterine contractions abnormal		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine contractions during pregnancy	Additional description: Uterine contractions during pregnancy		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vasa praevia	Additional description: Vasa praevia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Weight decrease neonatal	Additional description: Weight decrease neonatal		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Abdominal pain, Pyrexia	Additional description: Abdominal pain, Pyrexia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased, Blood glucose	Additional description: Blood pressure increased, Blood glucose		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased, Headache	Additional description: Blood pressure increased, Headache		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased, Pulmonary edema	Additional description: Blood pressure increased, Pulmonary edema		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholecystitis, Cholelithiasis, Pancreatitis	Additional description: Cholecystitis, Cholelithiasis, Pancreatitis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholestasis, HELLP	Additional description: Cholestasis, HELLP		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chorioamnionitis, Sepsis	Additional description: Chorioamnionitis, Sepsis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Cyst	Additional description: Cyst		
	subjects affected / exposed	1 / 1236 (0.08%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
Dehydration, Gastritis, Urinary tract infection	Additional description: Dehydration, Gastritis, Urinary tract infection		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Dysplasia	Additional description: Dysplasia		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Elevated hepatic enzymes, Pre-eclampsia, Glucose intolerance, Placental transfusion syndrome	Additional description: Elevated hepatic enzymes, Pre-eclampsia, Glucose intolerance, Placental transfusion syndrome		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Headache, Amylase increased	Additional description: Headache, Amylase increased		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Headache, Hypertension, Vision blurred	Additional description: Headache, Hypertension, Vision blurred		
	subjects affected / exposed	1 / 1236 (0.08%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
Headache, Pain in extremity	Additional description: Headache, Pain in extremity		
	subjects affected / exposed	1 / 1236 (0.08%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
Headache, Oedema, Hypertension	Additional description: Headache, Oedema, Hypertension		
	subjects affected / exposed	1 / 1236 (0.08%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	

Hypoglycaemia, Congenital cardiovascular anomaly	Additional description: Hypoglycaemia, Congenital cardiovascular anomaly		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia, Sepsis	Additional description: Hypoglycaemia, Sepsis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large for dates baby, Transient tachypnoea, Septal hypertrophy, Patent Ductus Arteriosus	Additional description: Large for dates baby, Transient tachypnoea, Septal hypertrophy, Patent Ductus Arteriosus		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal death due to Congenital cardiovascular anomaly, Pulmonary artery stenosis congenital	Additional description: Neonatal death due to Congenital cardiovascular anomaly, Pulmonary artery stenosis congenital		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory acidosis, Metabolic acidosis	Additional description: Neonatal respiratory acidosis, Metabolic acidosis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature baby, Death neonatal	Additional description: Premature baby, Death neonatal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature baby, Gastroschisis, Hyponatremia, Metabolic acidosis	Additional description: Premature baby, Gastroschisis, Hyponatremia, Metabolic acidosis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature baby, Hypoglycemia, Desaturation	Additional description: Premature baby, Hypoglycemia, Desaturation		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Premature cervical change, Polyhydramnios	Additional description: Premature cervical change, Polyhydramnios		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism symptoms	Additional description: Pulmonary embolism symptoms		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia, Low hemoglobin, Viral infection	Additional description: Tachycardia, Low hemoglobin, Viral infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Threatened labour, Cystitis	Additional description: Threatened labour, Cystitis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Unstable foetal lie, Polyhydramnios	Additional description: Unstable foetal lie, Polyhydramnios		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight loss, Hypernatraemia	Additional description: Weight loss, Hypernatraemia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			

Anaphylactic reaction	Additional description: Anaphylactic reaction		
	subjects affected / exposed	1 / 1236 (0.08%)	
	occurrences causally related to treatment / all	0 / 1	
	deaths causally related to treatment / all	0 / 0	
Milk allergy	Additional description: Milk allergy		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Reproductive system and breast disorders			
	Cervical polyp	Additional description: Cervical polyp	
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
Scrotal mass	Additional description: Scrotal mass		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Shortened cervix	Additional description: Shortened cervix		
	subjects affected / exposed	2 / 1236 (0.16%)	
	occurrences causally related to treatment / all	0 / 2	
	deaths causally related to treatment / all	0 / 0	
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
	subjects affected / exposed	3 / 1236 (0.24%)	
	occurrences causally related to treatment / all	0 / 3	
	deaths causally related to treatment / all	0 / 0	
Respiratory, thoracic and mediastinal disorders			
	Apnoea	Additional description: Apnoea	
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
Asthma			
	Additional description: Asthma		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hypoxia	Additional description: Hypoxia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal aspiration	Additional description: Neonatal aspiration		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neonatal respiratory distress syndrome	Additional description: Neonatal respiratory distress syndrome		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia, Respiratory distress	Additional description: Pneumonia, Respiratory distress		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia aspiration	Additional description: Pneumonia aspiration		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax	Additional description: Pneumothorax		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism	Additional description: Pulmonary embolism		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema	Additional description: Pulmonary oedema		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Mental disorder	Additional description: Mental disorder		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood bilirubin increased	Additional description: Blood bilirubin increased		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased	Additional description: Blood creatinine increased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood glucose	Additional description: Blood glucose		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood glucose decreased	Additional description: Blood glucose decreased		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood glucose increased	Additional description: Blood glucose increased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased	Additional description: Blood pressure increased		

subjects affected / exposed	6 / 1236 (0.49%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Blood pressure increased, Proteinuria	Additional description: Blood pressure increased, Proteinuria		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac murmur	Additional description: Cardiac murmur		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Foetal monitoring abnormal	Additional description: Foetal monitoring abnormal		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Foetal non-stress test abnormal	Additional description: Foetal non-stress test abnormal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glucose tolerance test abnormal	Additional description: Glucose tolerance test abnormal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ultrasound Doppler abnormal	Additional description: Ultrasound Doppler abnormal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ultrasound scan abnormal	Additional description: Ultrasound scan abnormal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urine output decreased	Additional description: Urine output decreased		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Abdominal injury	Additional description: Abdominal injury		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning	Additional description: Alcohol poisoning		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Brachial plexus injury	Additional description: Brachial plexus injury		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fracture	Additional description: Fracture		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Postoperative wound complication	Additional description: Postoperative wound complication		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Wound dehiscence	Additional description: Wound dehiscence		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Wound infection	Additional description: Wound infection		
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			

Ankyloglossia congenital	Additional description: Ankyloglossia congenital		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Cleft lip and palate	Additional description: Cleft lip and palate		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Congenital cardiovascular anomaly	Additional description: Congenital cardiovascular anomaly		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Congenital ectopic bladder	Additional description: Congenital ectopic bladder		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Congenital inguinal hernia	Additional description: Congenital inguinal hernia		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Congenital laryngeal stridor	Additional description: Congenital laryngeal stridor		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Cytogenetic abnormality	Additional description: Cytogenetic abnormality		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Encephalocele	Additional description: Encephalocele		
	subjects affected / exposed	0 / 1236 (0.00%)	
	occurrences causally related to treatment / all	0 / 0	
	deaths causally related to treatment / all	0 / 0	
Fallot's tetralogy	Additional description: Fallot's tetralogy		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glucose-6-phosphate dehydrogenase deficiency	Additional description: Glucose-6-phosphate dehydrogenase deficiency		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Holoprosencephaly	Additional description: Holoprosencephaly		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal aplasia	Additional description: Renal aplasia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Trisomy 13	Additional description: Trisomy 13		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Univentricular heart	Additional description: Univentricular heart		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular anomaly	Additional description: Vascular anomaly		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Cardiac arrest	Additional description: Cardiac arrest		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiomyopathy	Additional description: Cardiomyopathy		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palpitations	Additional description: Palpitations		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tachycardia foetal	Additional description: Tachycardia foetal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia	Additional description: Ventricular tachycardia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebral haemorrhage	Additional description: Cerebral haemorrhage		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebral ventricle dilatation	Additional description: Cerebral ventricle dilatation		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache	Additional description: Headache		
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Hypoxic-ischaemic encephalopathy	Additional description: Hypoxic-ischaemic encephalopathy		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Migraine	Additional description: Migraine		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Migraine, Syncope, Bell's palsy	Additional description: Migraine, Syncope, Bell's palsy		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Partial seizures	Additional description: Partial seizures		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subarachnoid haemorrhage	Additional description: Subarachnoid haemorrhage		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemolytic anaemia	Additional description: Haemolytic anaemia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Placental transfusion syndrome	Additional description: Placental transfusion syndrome		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo	Additional description: Vertigo		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Abdominal distension	Additional description: Abdominal distension	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Abdominal pain	Additional description: Abdominal pain	
subjects affected / exposed	2 / 1236 (0.16%)	
occurrences causally related to treatment / all	0 / 2	
deaths causally related to treatment / all	0 / 0	
Abdominal pain lower	Additional description: Abdominal pain lower	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Abdominal pain upper	Additional description: Abdominal pain upper	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Diarrhoea	Additional description: Diarrhoea	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Dyspepsia	Additional description: Dyspepsia	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Haematochezia	Additional description: Haematochezia	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Intestinal obstruction	Additional description: Intestinal obstruction	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences causally related to treatment / all	0 / 1	
deaths causally related to treatment / all	0 / 0	
Necrotising colitis	Additional description: Necrotising colitis	

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis	Additional description: Pancreatitis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage	Additional description: Upper gastrointestinal haemorrhage		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Volvulus	Additional description: Volvulus		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting	Additional description: Vomiting		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Acute fatty liver of pregnancy	Additional description: Acute fatty liver of pregnancy		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Biliary colic	Additional description: Biliary colic		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis	Additional description: Cholelithiasis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholestasis	Additional description: Cholestasis		

subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Cholestasis of pregnancy	Additional description: Cholestasis of pregnancy		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia	Additional description: Hyperbilirubinaemia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia neonatal	Additional description: Hyperbilirubinaemia neonatal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-alcoholic steatohepatitis	Additional description: Non-alcoholic steatohepatitis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Eczema	Additional description: Eczema		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis	Additional description: Nephrolithiasis		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal colic	Additional description: Renal colic		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal impairment	Additional description: Renal impairment		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ureteric obstruction	Additional description: Ureteric obstruction		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary incontinence	Additional description: Urinary incontinence		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary retention	Additional description: Urinary retention		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Foot deformity	Additional description: Foot deformity		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion	Additional description: Intervertebral disc protrusion		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myalgia	Additional description: Myalgia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain	Additional description: Musculoskeletal pain		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pain in extremity	Additional description: Pain in extremity		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pubic pain	Additional description: Pubic pain		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis	Additional description: Appendicitis		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Arthritis bacterial	Additional description: Arthritis bacterial		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchiolitis	Additional description: Bronchiolitis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchitis	Additional description: Bronchitis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cellulitis	Additional description: Cellulitis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chorioamnionitis	Additional description: Chorioamnionitis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital pneumonia	Additional description: Congenital pneumonia		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometritis	Additional description: Endometritis		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Endometritis, Urinary tract infection	Additional description: Endometritis, Urinary tract infection		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral	Additional description: Gastroenteritis viral		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Impaired gastric emptying	Additional description: Impaired gastric emptying		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection, Endometritis, Left Mastitis, Urinary tract infection	Additional description: Infection, Endometritis, Left Mastitis, Urinary tract infection		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza	Additional description: Influenza		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis viral	Additional description: Meningitis viral		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastitis	Additional description: Mastitis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Moraxella infection	Additional description: Moraxella infection		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia	Additional description: Pneumonia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection	Additional description: Postoperative wound infection		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis	Additional description: Pyelonephritis		
subjects affected / exposed	6 / 1236 (0.49%)		
occurrences causally related to treatment / all	0 / 6		
deaths causally related to treatment / all	0 / 0		
Sepsis	Additional description: Sepsis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis neonatal	Additional description: Sepsis neonatal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Streptococcal urinary tract infection	Additional description: Streptococcal urinary tract infection		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Viral infection	Additional description: Viral infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Cow's milk intolerance, Gastroesophageal reflux disease	Additional description: Cow's milk intolerance, Gastroesophageal reflux disease		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration	Additional description: Dehydration		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus	Additional description: Diabetes mellitus		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control	Additional description: Diabetes mellitus inadequate control		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis	Additional description: Diabetic ketoacidosis		

subjects affected / exposed	2 / 1236 (0.16%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Fluid overload	Additional description: Fluid overload		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Food intolerance	Additional description: Food intolerance		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia	Additional description: Hyperglycaemia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ketosis	Additional description: Ketosis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic syndrome	Additional description: Metabolic syndrome		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus	Additional description: Type 2 diabetes mellitus		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	active_mother	active_infant	placebo_infant
Total subjects affected by non-serious adverse events			
subjects affected / exposed	910 / 1227 (74.16%)	197 / 1364 (14.44%)	238 / 1374 (17.32%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon	Additional description: Acrochordon		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	4 / 1374 (0.29%)
occurrences (all)	0	1	4
Melanocytic naevus			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Vascular disorders			
Gestational hypertension	Additional description: Gestational hypertension		
subjects affected / exposed	20 / 1227 (1.63%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	20	0	0
Hypertension	Additional description: Hypertension		
subjects affected / exposed	49 / 1227 (3.99%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	49	0	0
Subgaleal haematoma	Additional description: Subgaleal haematoma		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	0	1	1
Hot flush			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Labile hypertension			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Thrombosis			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Thrombophlebitis superficial			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Thrombophlebitis			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Labile blood pressure			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Hypovolaemic shock			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Haematoma			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Abortion induced	Additional description: Abortion induced		
subjects affected / exposed	1 / 1227 (0.08%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	1	1	0
Bartholin's cyst removal	Additional description: Bartholin's cyst removal		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
External cephalic version	Additional description: Failed external cephalic version		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Respiratory support	Additional description: Respiratory support		
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences (all)	0	2	0
Transfusion	Additional description: Transfusion		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0

Wound treatment subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Tooth extraction subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Office visit subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Ureteral stent insertion subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Surgery subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Tooth repair subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Physiotherapy subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
General anaesthesia subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Forceps delivery subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Episiotomy subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Pregnancy, puerperium and perinatal conditions			
Foetal growth restriction	Additional description: Foetal growth restriction		
subjects affected / exposed	0 / 1227 (0.00%)	9 / 1364 (0.66%)	14 / 1374 (1.02%)
occurrences (all)	0	9	14
Foetal hypokinesia	Additional description: Foetal hypokinesia		

subjects affected / exposed	93 / 1227 (7.58%)	18 / 1364 (1.32%)	27 / 1374 (1.97%)
occurrences (all)	93	18	27
Gestational diabetes	Additional description: Gestational diabetes		
subjects affected / exposed	89 / 1227 (7.25%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	89	0	1
Jaundice neonatal	Additional description: Jaundice neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	14 / 1364 (1.03%)	17 / 1374 (1.24%)
occurrences (all)	0	14	17
Polyhydramnios	Additional description: Polyhydramnios		
subjects affected / exposed	8 / 1227 (0.65%)	2 / 1364 (0.15%)	1 / 1374 (0.07%)
occurrences (all)	8	2	1
Postpartum haemorrhage	Additional description: Postpartum haemorrhage		
subjects affected / exposed	25 / 1227 (2.04%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	25	0	0
Pre-eclampsia	Additional description: Pre-eclampsia		
subjects affected / exposed	26 / 1227 (2.12%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	26	0	0
Premature baby	Additional description: Premature baby		
subjects affected / exposed	3 / 1227 (0.24%)	39 / 1364 (2.86%)	26 / 1374 (1.89%)
occurrences (all)	3	39	26
Premature rupture of membranes	Additional description: Premature rupture of membranes		
subjects affected / exposed	18 / 1227 (1.47%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	18	1	1
Uterine contractions during pregnancy	Additional description: Uterine contractions during pregnancy		
subjects affected / exposed	37 / 1227 (3.02%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	37	0	1
Born before arrival	Additional description: Born before arrival		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Contractions, Premature rupture of membranes	Additional description: Contractions, Premature rupture of membranes		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Contractions, Vaginal haemorrhage	Additional description: Contractions, Vaginal haemorrhage		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Contractions, Vaginal haemorrhage, Premature rupture of membranes	Additional description: Contractions, Vaginal haemorrhage, Premature rupture of membranes		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Low birth weight baby, Oligohydramnios	Additional description: Low birth weight baby, Oligohydramnios		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Placental transfusion syndrome, Oligohydramnios	Additional description: Placental transfusion syndrome, Oligohydramnios		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower, Contractions	Additional description: Abdominal pain lower, Contractions		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abortion threatened	Additional description: Abortion threatened		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Caesarean section	Additional description: Caesarean section		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Cephalhaematoma	Additional description: Cephalhaematoma		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	0	0	2
Cervical incompetence	Additional description: Cervical incompetence		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Prenatal screening test abnormal			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Low birth weight baby	Additional description: Low birth weight baby		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	2 / 1374 (0.15%)
occurrences (all)	0	1	2
Amniorrhoea	Additional description: Amniorrhoea		

subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Placenta accreta	Additional description: Placenta accreta		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Labour pain			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Meconium stain			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Foetal macrosomia			
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	6 / 1374 (0.44%)
occurrences (all)	0	2	6
Labour induction			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Imminent abortion			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Meconium abnormal			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	0	1	1
Vomiting in pregnancy			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Umbilical cord prolapse			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Retained placenta or membranes			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Placental disorder			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Placenta praevia			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Labour			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Large for dates baby			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Foetal distress syndrome			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Placental insufficiency			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain	Additional description: Chest pain		
subjects affected / exposed	20 / 1227 (1.63%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	20	0	0
Fatigue	Additional description: Fatigue		
subjects affected / exposed	35 / 1227 (2.85%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	35	0	0
Malaise	Additional description: Malaise		
subjects affected / exposed	21 / 1227 (1.71%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	21	0	0
Oedema	Additional description: Oedema		
subjects affected / exposed	33 / 1227 (2.69%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	33	0	0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	93 / 1227 (7.58%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	93	0	0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	13 / 1227 (1.06%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	13	0	0
Abdominal cramping, Vaginal discharge	Additional description: Abdominal cramping, Vaginal discharge		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort, Pelvic pain	Additional description: Abdominal discomfort, Pelvic pain		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain, Amniotic fluid leak	Additional description: Abdominal pain, Amniotic fluid leak		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain, Back pain	Additional description: Abdominal pain, Back pain		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain, Contractions	Additional description: Abdominal pain, Contractions		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain, Pyrexia	Additional description: Abdominal pain, Pyrexia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain, Vaginal discharge	Additional description: Abdominal pain, Vaginal discharge		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain, Vaginal haemorrhage	Additional description: Abdominal pain, Vaginal haemorrhage		
subjects affected / exposed	6 / 1227 (0.49%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	6	0	0
Abdominal pain lower, Back pain	Additional description: Abdominal pain lower, Back pain		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower, Vaginal haemorrhage, Back pain	Additional description: Abdominal pain lower, Vaginal haemorrhage, Back pain		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper, Dyspnoea	Additional description: Abdominal pain upper, Dyspnoea		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper, Headache	Additional description: Abdominal pain upper, Headache		

subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Abdominal pain upper, Nausea	Additional description: Abdominal pain upper, Nausea		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper, Headache, Oedema peripheral	Additional description: Abdominal pain upper, Headache, Oedema peripheral		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain, Diarrhoea, Back pain, Vaginal discharge	Additional description: Abdominal pain, Diarrhoea, Back pain, Vaginal discharge		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain, Back pain, Visual impairment	Additional description: Abdominal pain, Back pain, Visual impairment		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain, Headache, Oedema peripheral	Additional description: Abdominal pain, Headache, Oedema peripheral		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain, Malaise, Heart rate increased, Dehydration	Additional description: Abdominal pain, Malaise, Heart rate increased, Dehydration		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abdominal pain, Vaginal haemorrhage, Cholestasis of pregnancy	Additional description: Abdominal pain, Vaginal haemorrhage, Cholestasis of pregnancy		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal pain, Vomiting, Tachypnoea	Additional description: Abdominal pain, Vomiting, Tachypnoea		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Back pain, Constipation	Additional description: Back pain, Constipation		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Back pain, Contractions	Additional description: Back pain, Contractions		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0

Back pain, Pollakiuria subjects affected / exposed occurrences (all)	Additional description: Back pain, Pollakiuria		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Back pain, Right sided pain, Vomiting subjects affected / exposed occurrences (all)	Additional description: Back pain, Right sided pain, Vomiting		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Back pain, Oropharyngeal pain, Diarrhoea, Pollakiuria subjects affected / exposed occurrences (all)	Additional description: Back pain, Oropharyngeal pain, Diarrhoea, Pollakiuria		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood glucose, Urine ketone body present subjects affected / exposed occurrences (all)	Additional description: Blood glucose and Urine ketone body present		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood glucose increased, Nausea subjects affected / exposed occurrences (all)	Additional description: Blood glucose increased, Nausea		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure increased, Dyspnoea subjects affected / exposed occurrences (all)	Additional description: Blood pressure increased, Dyspnoea		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure increased, Anogenital warts subjects affected / exposed occurrences (all)	Additional description: Blood pressure increased, Anogenital warts		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure increased, Headache subjects affected / exposed occurrences (all)	Additional description: Blood pressure increased, Headache		
	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure increased, Oedema peripheral subjects affected / exposed occurrences (all)	Additional description: Blood pressure increased, Oedema peripheral		
	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure increased, Visual impairment subjects affected / exposed occurrences (all)	Additional description: Blood pressure increased, Visual impairment		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure increased, Headache, Blurred vision subjects affected / exposed occurrences (all)	Additional description: Blood pressure increased, Headache, Blurred vision		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0

Blood pressure increased, Oedema subjects affected / exposed occurrences (all)	Additional description: Blood pressure increased, Oedema		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vision blurred, Dizziness, Protein urine subjects affected / exposed occurrences (all)	Additional description: Vision blurred, Dizziness, Protein urine		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Chest discomfort, Cough subjects affected / exposed occurrences (all)	Additional description: Chest discomfort, Cough		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Chorioamnionitis, Creatine urine increased subjects affected / exposed occurrences (all)	Additional description: Chorioamnionitis, Creatine urine increased		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Constipation, Urinary tract infection, Vaginal discharge subjects affected / exposed occurrences (all)	Additional description: Constipation, Urinary tract infection, Vaginal discharge		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Contractions, Pelvic pain subjects affected / exposed occurrences (all)	Additional description: Contractions, Pelvic pain		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Contractions, Candida infection subjects affected / exposed occurrences (all)	Additional description: Contractions, Candida infection		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Contractions, Vomiting subjects affected / exposed occurrences (all)	Additional description: Contractions, Vomiting		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Diarrhoea, Nausea, Sensation of pressure, Vaginal discharge subjects affected / exposed occurrences (all)	Additional description: Diarrhoea, Nausea, Sensation of pressure, Vaginal discharge		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dry eye, Dry mouth subjects affected / exposed occurrences (all)	Additional description: Dry eye, Dry mouth		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dyspnoea, Asthenia, Vision blurred subjects affected / exposed occurrences (all)	Additional description: Dyspnoea, Asthenia, Vision blurred		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dyspnoea, Diarrhoea, Myalgia, Abdominal pain, Back pain	Additional description: Dyspnoea, Diarrhoea, Myalgia, Abdominal pain, Back pain		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Dyspnoea, Headache, Oedema, Protein urine, Blood urine	Additional description: Dyspnoea, Headache, Oedema, Protein urine, Blood urine		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Dyspnoea, Chest pain	Additional description: Dyspnoea, Chest pain		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Fatigue, Abdominal pain, Nausea	Additional description: Fatigue, Abdominal pain, Nausea		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Fatigue, Oropharyngeal pain, Abdominal pain upper	Additional description: Fatigue, Oropharyngeal pain, Abdominal pain upper		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Amylase increased	Additional description: Headache, Amylase increased		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Arthralgia	Additional description: Headache, Arthralgia		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Headache, Back pain	Additional description: Headache, Back pain		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Diarrhoea	Additional description: Headache, Diarrhoea		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Oedema	Additional description: Headache, Oedema		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Oedema peripheral	Additional description: Headache, Oedema peripheral		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Pain in extremity	Additional description: Headache, Pain in extremity		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Protein urine	Additional description: Headache, Protein urine		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Proteinuria	Additional description: Headache, Proteinuria		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Urine protein/creatinine ratio	Additional description: Headache, Urine protein/creatinine ratio		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Dizziness, Night sweats	Additional description: Headache, Dizziness, Night sweats		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Ear pain, Nausea, Dyspepsia	Additional description: Headache, Ear pain, Nausea, Dyspepsia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Pain in extremity, Diarrhoea	Additional description: Headache, Pain in extremity, Diarrhoea		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Nausea, Back pain	Additional description: Headache, Nausea, Back pain		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Oedema, Visual impairment			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Oedema peripheral, Visual impairment, Abdominal pain upper, Dyspepsia	Additional description: Headache, Oedema peripheral, Visual impairment, Abdominal pain upper, Dyspepsia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Oedema, Abdominal pain, Hypertension	Additional description: Headache, Oedema, Abdominal pain, Hypertension		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0

Headache, Oedema, Abdominal pain upper, Malaise	Additional description: Headache, Oedema, Abdominal pain upper, Malaise		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Oedema, Blood pressure increased, Protein urine	Additional description: Headache, Oedema, Blood pressure increased, Protein urine		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Headache, Dysuria, Candida infection	Additional description: Headache, Dysuria, Candida infection		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Visual impairment, Nausea, Diarrhoea	Additional description: Headache, Visual impairment, Nausea, Diarrhoea		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Headache, Vomiting, Hypertension	Additional description: Headache, Vomiting, Hypertension		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Hypertension, Oedema peripheral	Additional description: Hypertension, Oedema peripheral		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Hypertension, Proteinuria	Additional description: Hypertension, Proteinuria		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Hypertension, Heart rate increased, Palpitations	Additional description: Hypertension, Heart rate increased, Palpitations		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Pain in extremity, Oedema peripheral, Haemoptysis	Additional description: Pain in extremity, Oedema peripheral, Haemoptysis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Lethargy, Dizziness, Dyspepsia	Additional description: Lethargy, Dizziness, Dyspepsia		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness, Foetal hypokinesia	Additional description: Loss of consciousness, Foetal hypokinesia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0

Malaise, Oedema peripheral subjects affected / exposed occurrences (all)	Additional description: Malaise, Oedema peripheral		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Maternal exposure during pregnancy to Varicella subjects affected / exposed occurrences (all)	Additional description: Maternal exposure during pregnancy to Varicella		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Migraine, Syncope, Bell's palsy subjects affected / exposed occurrences (all)	Additional description: Migraine, Syncope, Bell's palsy		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Musculoskeletal pain, Urinary tract infection, Dyspepsia subjects affected / exposed occurrences (all)	Additional description: Musculoskeletal pain, Urinary tract infection, Dyspepsia		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Myalgia, Vaginal discharge subjects affected / exposed occurrences (all)	Additional description: Myalgia, Vaginal discharge		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Nausea, Palpitations, Insomnia subjects affected / exposed occurrences (all)	Additional description: Nausea, Palpitations, Insomnia		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Jaundice neonatal, Hypoglycaemia neonatal, Sepsis neonatal subjects affected / exposed occurrences (all)	Additional description: Jaundice neonatal, Hypoglycaemia neonatal, Sepsis neonatal		
	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Oedema peripheral, Dizziness subjects affected / exposed occurrences (all)	Additional description: Oedema peripheral, Dizziness		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Oedema peripheral, Candida infection subjects affected / exposed occurrences (all)	Additional description: Oedema peripheral, Candida infection		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Oedema peripheral, Vulvovaginal swelling subjects affected / exposed occurrences (all)	Additional description: Oedema peripheral, Vulvovaginal swelling		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Pain in extremity, Vaginal haemorrhage, Abdominal pain subjects affected / exposed occurrences (all)	Additional description: Pain in extremity, Vaginal haemorrhage, Abdominal pain		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0

Premature rupture of membranes, Chorioamnionitis	Additional description: Premature rupture of membranes, Chorioamnionitis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Premature rupture of membranes, Vaginal haemorrhage	Additional description: Premature rupture of membranes, Vaginal haemorrhage		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Protein urine, Oedema peripheral	Additional description: Protein urine, Oedema peripheral		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Proteinuria, Oedema peripheral	Additional description: Proteinuria, Oedema peripheral		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Pruritus, Back pain, Oedema	Additional description: Pruritus, Back pain, Oedema		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Rash, Foetal hypokinesia	Additional description: Rash, Foetal hypokinesia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Rash, Pyrexia	Additional description: Rash, Pyrexia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Reflux gastritis, Ketone body in urine	Additional description: Reflux gastritis, Ketone body in urine		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Sciatica, Skin infection	Additional description: Sciatica, Skin infection		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Shoulder dystocia, Erb's palsy	Additional description: Shoulder dystocia, Erb's palsy		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	0	0	2
Musculoskeletal pain, Rash	Additional description: Shoulder pain, Rash		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Thirst, Hyperhidrosis	Additional description: Thirst, Hyperhidrosis		

subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vaginal discomfort, Back pain, Dysuria	Additional description: Vaginal discomfort, Back pain, Dysuria		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vaginal haemorrhage, Pain	Additional description: Vaginal haemorrhage, Pain		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vaginal haemorrhage, Pelvic pain	Additional description: Vaginal haemorrhage, Pelvic pain		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vaginal haemorrhage, Vaginal discharge	Additional description: Vaginal haemorrhage, Vaginal discharge		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vaginal haemorrhage, Diarrhoea, Incontinence	Additional description: Vaginal haemorrhage, Diarrhoea, Incontinence		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Visual impairment, Dyspnoea, Polyhydramnios	Additional description: Visual impairment, Dyspnoea, Polyhydramnios		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vomiting, Dizziness, Migraine	Additional description: Vomiting, Dizziness, Migraine		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain, Back pain, Vaginal discharge	Additional description: Abdominal pain, Back pain, Vaginal discharge		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Asthenia	Additional description: Asthenia		
subjects affected / exposed occurrences (all)	7 / 1227 (0.57%) 7	0 / 1364 (0.00%) 0	7 / 1374 (0.51%) 7
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Drug level changed			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Fat necrosis			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
General symptom			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Sensation of pressure			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Pre-existing condition improved			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	11 / 1227 (0.90%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	11	0	0
Irritability			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Impaired healing			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Hypothermia neonatal			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Feeling abnormal			

subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Face oedema subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Feeling hot subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Immune system disorders			
ABO incompatibility	Additional description: ABO incompatibility		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	3 / 1364 (0.22%) 3	0 / 1374 (0.00%) 0
Drug hypersensitivity	Additional description: Drug hypersensitivity		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
House dust allergy subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Seasonal allergy subjects affected / exposed occurrences (all)	8 / 1227 (0.65%) 8	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Reproductive system and breast disorders			
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed occurrences (all)	32 / 1227 (2.61%) 32	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed occurrences (all)	14 / 1227 (1.14%) 14	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed occurrences (all)	56 / 1227 (4.56%) 56	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Bartholinitis	Additional description: Bartholinitis		

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Breast cyst	Additional description: Breast cyst		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Breast pain	Additional description: Breast pain		
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Breast tenderness	Additional description: Breast tenderness		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Cervix disorder	Additional description: Cervix disorder		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain	Additional description: Vulvovaginal pain		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Vulvovaginal burning sensation	Additional description: Vulvovaginal burning sensation		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Coital bleeding	Additional description: Coital bleeding		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	7	0	0
Uterine cervical pain			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Cervical friability			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Cervix haematoma uterine			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Vaginal lesion			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Varicose veins vulval			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Vaginal odour			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Vaginal laceration			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Uterine spasm			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Uterine atony			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Uterine haemorrhage			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough	Additional description: Cough		
subjects affected / exposed	16 / 1227 (1.30%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	16	0	0
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	86 / 1227 (7.01%)	1 / 1364 (0.07%)	2 / 1374 (0.15%)
occurrences (all)	86	1	2
Epistaxis	Additional description: Epistaxis		

subjects affected / exposed	14 / 1227 (1.14%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	14	0	0
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	19 / 1227 (1.55%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	19	0	0
Atelectasis, Pneumothorax	Additional description: Atelectasis, Pneumothorax		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	5 / 1227 (0.41%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	5	0	0
Wheezing			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Transient tachypnoea of the newborn			
subjects affected / exposed	0 / 1227 (0.00%)	5 / 1364 (0.37%)	2 / 1374 (0.15%)
occurrences (all)	0	5	2
Sleep apnoea syndrome			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0

Productive cough subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Pleural effusion subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	8 / 1227 (0.65%) 8	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Pulmonary haemorrhage neonatal subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Psychiatric disorders			
Insomnia	Additional description: Insomnia		
subjects affected / exposed occurrences (all)	16 / 1227 (1.30%) 16	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Anxiety	Additional description: Anxiety		
subjects affected / exposed occurrences (all)	7 / 1227 (0.57%) 7	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Anxiety attack	Additional description: Anxiety attack		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Breath holding	Additional description: Breath holding		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Depressed mood	Additional description: Depressed mood		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Depression	Additional description: Depression		
subjects affected / exposed occurrences (all)	4 / 1227 (0.33%) 4	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Disturbance in attention	Additional description: Disturbance in attention		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Postpartum depression			

subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Sleep disorder			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Panic attack			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Nervousness			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Mood swings			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia neonatal	Additional description: Hyperbilirubinaemia neonatal		
subjects affected / exposed	0 / 1227 (0.00%)	14 / 1364 (1.03%)	18 / 1374 (1.31%)
occurrences (all)	0	14	18
Cholecystitis	Additional description: Cholecystitis		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Hepatomegaly			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Hepatic pain			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood pressure increased	Additional description: Blood pressure increased		
subjects affected / exposed	52 / 1227 (4.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	52	0	0
Protein urine present	Additional description: Protein urine present		
subjects affected / exposed	13 / 1227 (1.06%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	13	0	0
Serum ferritin	Additional description: Serum ferritin		

subjects affected / exposed	14 / 1227 (1.14%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	14	1	0
Blood pressure increased, Protein in urine	Additional description: Blood pressure increased, Protein in urine		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Blood pressure increased, Proteinuria	Additional description: Blood pressure increased, Proteinuria		
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	4	0	1
Albumin urine	Additional description: Albumin urine test		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	3	0	2
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Blood bicarbonate	Additional description: Blood bicarbonate		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin	Additional description: Blood bilirubin		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Blood calcium	Additional description: Blood calcium		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Blood chloride	Additional description: Blood chloride		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Blood creatine	Additional description: Blood creatine		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Blood fibrinogen increased	Additional description: Blood fibrinogen increased		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Blood gases abnormal	Additional description: Blood gases abnormal		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	3 / 1374 (0.22%)
occurrences (all)	0	0	3
Blood iron decreased	Additional description: Blood iron decreased		
subjects affected / exposed	8 / 1227 (0.65%)	0 / 1364 (0.00%)	3 / 1374 (0.22%)
occurrences (all)	8	0	3
Blood lactate dehydrogenase	Additional description: Blood lactate dehydrogenase		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Blood potassium decreased	Additional description: Blood potassium decreased		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Blood pressure abnormal	Additional description: Blood pressure abnormal		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Blood pressure decreased	Additional description: Blood pressure decreased		
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Blood sodium	Additional description: Blood sodium		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Blood sodium abnormal	Additional description: Blood sodium abnormal		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone	Additional description: Blood thyroid stimulating hormone		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Blood urea	Additional description: Blood urea		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Blood uric acid increased	Additional description: Blood uric acid increased		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Blood urine	Additional description: Blood urine		

subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Human rhinovirus test positive	Additional description: Human rhinovirus test positive		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Streptococcus test positive	Additional description: Streptococcus test positive		
subjects affected / exposed occurrences (all)	7 / 1227 (0.57%) 7	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Respiratory syncytial virus test positive	Additional description: Respiratory syncytial virus test positive		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Venous oxygen partial pressure decreased	Additional description: Venous oxygen partial pressure decreased		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Total bile acids increased	Additional description: Total bile acids increased		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Fibronectin increased	Additional description: Fibronectin increased		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Amniotic fluid volume increased	Additional description: Amniotic fluid volume increased		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Amniotic fluid volume decreased	Additional description: Amniotic fluid volume decreased		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Urine cannabinoids increased			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Urine analysis abnormal			
subjects affected / exposed occurrences (all)	5 / 1227 (0.41%) 5	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Hepatic enzyme increased			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Gastric pH decreased			
subjects affected / exposed	8 / 1227 (0.65%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	8	0	0
Total bile acids			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Base excess			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Urine ketone body present			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Urine protein/creatinine ratio increased			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Urine albumin/creatinine ratio increased			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Foetal heart rate abnormal			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	3 / 1374 (0.22%)
occurrences (all)	3	0	3
Urine leukocyte esterase positive			
subjects affected / exposed	6 / 1227 (0.49%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	6	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Vitamin B12			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Tri-iodothyronine			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Serum ferritin decreased			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Platelet count decreased			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Platelet count			
subjects affected / exposed	3 / 1227 (0.24%)	2 / 1364 (0.15%)	1 / 1374 (0.07%)
occurrences (all)	3	2	1
Physical examination			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Oxygen saturation decreased			
subjects affected / exposed	2 / 1227 (0.16%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	2	1	1
Heart rate increased			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Heart rate abnormal			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Haemoglobin			
subjects affected / exposed	12 / 1227 (0.98%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	12	0	2
Haemoglobin decreased			
subjects affected / exposed	12 / 1227 (0.98%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	12	0	0
Haematocrit			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	2	0	2
Glycosylated haemoglobin			
subjects affected / exposed	6 / 1227 (0.49%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	6	0	0
Glucose urine present			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Glucose urine			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Glucose tolerance test			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Fall	Additional description: Fall		
subjects affected / exposed	9 / 1227 (0.73%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	9	0	1
Accidental overdose	Additional description: Accidental overdose		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Accidental poisoning	Additional description: Accidental poisoning		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Animal bite	Additional description: Animal bite (dog)		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Ankle fracture	Additional description: Ankle fracture		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture	Additional description: Clavicle fracture		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Maternal exposure during pregnancy to Hand-foot-and-mouth disease	Additional description: Maternal exposure during pregnancy to Hand-foot-and-mouth disease		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Foreign body	Additional description: Foreign body		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Skeletal injury			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Excoriation			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Uterine rupture			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Seroma			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Road traffic accident			
subjects affected / exposed	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	7	0	0
Perineal laceration			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Femoral nerve injury			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Additional description: Congenital cardiovascular anomaly			
Congenital cardiovascular anomaly	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	0	1	1
Additional description: Apert's syndrome			
Apert's syndrome	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Additional description: Atrial septal defect			
Atrial septal defect	1 / 1227 (0.08%)	1 / 1364 (0.07%)	2 / 1374 (0.15%)
occurrences (all)	1	1	2
Additional description: Cataract congenital			
Cataract congenital	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Additional description: Congenital anomaly			
Congenital anomaly	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Additional description: Congenital central nervous system anomaly			
Congenital central nervous system anomaly	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Additional description: Cryptorchism			
Cryptorchism	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Additional description: Developmental hip dysplasia			
Developmental hip dysplasia	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	0	1	1
Additional description: Congenital skin dimples			
Congenital skin dimples			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	3 / 1374 (0.22%)
occurrences (all)	0	0	3
Skeletal dysplasia	Additional description: Skeletal dysplasia		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Congenital naevus	Additional description: Congenital naevus		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	0	1	1
Naevus flammeus	Additional description: Naevus flammeus		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Ectopic kidney			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Skull malformation	Additional description: Skull malformation		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Anomaly of external ear congenital			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Congenital Eustachian tube anomaly	Additional description: Congenital Eustachian tube anomaly		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Congenital oral malformation			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Laryngomalacia			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Trisomy 18			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Congenital eye naevus			
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences (all)	0	2	0
Congenital hydronephrosis			

subjects affected / exposed	1 / 1227 (0.08%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences (all)	1	2	0
Macrocephaly			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Congenital adrenal gland hypoplasia			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Trisomy 21			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Talipes			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Sebaceous naevus			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Pyloric stenosis			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Pulmonary malformation			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Pulmonary artery stenosis congenital			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Patent ductus arteriosus			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Limb malformation			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Kidney duplex			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Hypospadias			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Hydrocele			
subjects affected / exposed	0 / 1227 (0.00%)	3 / 1364 (0.22%)	3 / 1374 (0.22%)
occurrences (all)	0	3	3
Heart disease congenital			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Haemangioma congenital			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	2 / 1374 (0.15%)
occurrences (all)	0	1	2
Gastroschisis			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Galactosaemia			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Exomphalos			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Congenital hypothyroidism			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Palpitations	Additional description: Palpitations		
subjects affected / exposed	14 / 1227 (1.14%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	14	0	0
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed	1 / 1227 (0.08%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	1	1	1
Bradycardia foetal	Additional description: Bradycardia foetal		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	3 / 1374 (0.22%)
occurrences (all)	0	1	3
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0

Bundle branch block left subjects affected / exposed occurrences (all)	Additional description: Bundle branch block left		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0	0	0
Cardiomegaly subjects affected / exposed occurrences (all)	Additional description: Cardiomegaly		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0	0	0
Cyanosis subjects affected / exposed occurrences (all)	Additional description: Cyanosis		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	3 / 1374 (0.22%)
	0	0	3
Foetal heart rate deceleration abnormality subjects affected / exposed occurrences (all)	1 / 1227 (0.08%)	1 / 1364 (0.07%)	3 / 1374 (0.22%)
	1	1	3
Bradycardia neonatal subjects affected / exposed occurrences (all)	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	0	0	1
Pericardial cyst subjects affected / exposed occurrences (all)	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	0	0	1
Wolff-Parkinson-White syndrome subjects affected / exposed occurrences (all)	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	1	0	0
Ventricular extrasystoles subjects affected / exposed occurrences (all)	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	1	0	0
Tachycardia subjects affected / exposed occurrences (all)	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	7	0	0
Tachycardia foetal subjects affected / exposed occurrences (all)	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	0	0	1
Sinus tachycardia subjects affected / exposed occurrences (all)	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	2	0	0
Pericarditis			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Klinefelter's syndrome			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Extrasystoles			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Carpal tunnel syndrome	Additional description: Carpal tunnel syndrome		
subjects affected / exposed	19 / 1227 (1.55%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	19	0	0
Dizziness	Additional description: Dizziness		
subjects affected / exposed	64 / 1227 (5.22%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	64	0	0
Headache	Additional description: Headache		
subjects affected / exposed	276 / 1227 (22.49%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	276	0	0
Hypoaesthesia	Additional description: Hypoaesthesia		
subjects affected / exposed	12 / 1227 (0.98%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	12	0	0
Migraine	Additional description: Migraine		
subjects affected / exposed	26 / 1227 (2.12%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	26	0	0
Sciatica	Additional description: Sciatica		
subjects affected / exposed	12 / 1227 (0.98%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	12	0	0
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Apraxia	Additional description: Apraxia		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Burning sensation	Additional description: Burning sensation		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Convulsion	Additional description: Convulsion		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Depressed level of consciousness	Additional description: Depressed level of consciousness		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemic seizure	Additional description: Hyperglycaemic seizure		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
VIIth nerve paralysis			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
VIth nerve paralysis			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Tension headache			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Somnolence			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Sinus headache			

subjects affected / exposed	5 / 1227 (0.41%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	5	0	0
Presyncope			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Paraesthesia			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Nerve compression			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Loss of consciousness			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Hypotonic-hyporesponsive episode			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia	Additional description: Anaemia		
subjects affected / exposed	63 / 1227 (5.13%)	1 / 1364 (0.07%)	3 / 1374 (0.22%)
occurrences (all)	63	1	3
Splenic cyst			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Thrombocytopenia neonatal			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	0	0	2
Thrombocytopenia			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0

Lymphadenopathy subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Ear and labyrinth disorders			
Acoustic stimulation tests abnormal subjects affected / exposed occurrences (all)	Additional description: Acoustic stimulation tests abnormal 2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Deafness subjects affected / exposed occurrences (all)	Additional description: Deafness 0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	Additional description: Ear pain 2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Ear discomfort subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Tinnitus subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Eye disorders			
Conjunctivitis subjects affected / exposed occurrences (all)	Additional description: Conjunctivitis 14 / 1227 (1.14%) 14	1 / 1364 (0.07%) 1	6 / 1374 (0.44%) 6
Vision Blurred subjects affected / exposed occurrences (all)	Additional description: Vision Blurred 20 / 1227 (1.63%) 20	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Visual impairment subjects affected / exposed occurrences (all)	Additional description: Visual impairment 53 / 1227 (4.32%) 53	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Diabetic retinopathy subjects affected / exposed occurrences (all)	Additional description: Diabetic retinopathy 0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	Additional description: Dry eye 0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Sunset eyes	Additional description: Sunset Eyes/ Setting sun phenomenon		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Chorioretinopathy	Additional description: Chorioretinopathy		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Visual field defect			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Scintillating scotoma			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Photopsia			
subjects affected / exposed	10 / 1227 (0.81%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	10	0	0
Photophobia			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Periorbital oedema			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	8 / 1227 (0.65%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	8	0	0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	57 / 1227 (4.65%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	57	0	0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	82 / 1227 (6.68%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	82	0	0

Diarrhoea	Additional description: Diarrhoea		
	33 / 1227 (2.69%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
subjects affected / exposed	33	0	1
occurrences (all)			
Constipation	Additional description: Constipation		
	46 / 1227 (3.75%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
subjects affected / exposed	46	0	2
occurrences (all)			
Dyspepsia	Additional description: Dyspepsia		
	126 / 1227 (10.27%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
subjects affected / exposed	126	1	0
occurrences (all)			
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
	61 / 1227 (4.97%)	5 / 1364 (0.37%)	4 / 1374 (0.29%)
subjects affected / exposed	61	5	4
occurrences (all)			
Nausea	Additional description: Nausea		
	85 / 1227 (6.93%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
subjects affected / exposed	85	0	0
occurrences (all)			
Toothache	Additional description: Toothache		
	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
subjects affected / exposed	7	0	0
occurrences (all)			
Vomiting	Additional description: Vomiting		
	90 / 1227 (7.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
subjects affected / exposed	90	0	0
occurrences (all)			
Abdominal pain, Nausea	Additional description: Abdominal pain, Nausea		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
subjects affected / exposed	1	0	0
occurrences (all)			
Constipation, Dyspepsia	Additional description: Constipation, Dyspepsia		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
subjects affected / exposed	1	0	0
occurrences (all)			
Abdominal discomfort	Additional description: Abdominal discomfort		
	8 / 1227 (0.65%)	0 / 1364 (0.00%)	6 / 1374 (0.44%)
subjects affected / exposed	8	0	6
occurrences (all)			
Dry mouth	Additional description: Dry mouth		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
subjects affected / exposed	1	0	0
occurrences (all)			
Gastrointestinal inflammation	Additional description: Gastrointestinal inflammation		

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Tooth abscess			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Periodontal disease			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Oesophageal spasm			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Lip swelling			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Intestinal dilatation			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Infantile colic			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	10 / 1227 (0.81%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	10	0	0
Haematemesis			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Gingival swelling			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Gingival bleeding			
subjects affected / exposed	5 / 1227 (0.41%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	5	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	5 / 1227 (0.41%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	5	0	0
Frequent bowel movements			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Food poisoning			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Oral pain			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Pruritus	Additional description: Pruritus		
subjects affected / exposed	48 / 1227 (3.91%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	48	0	0

Rash	Additional description: Rash		
subjects affected / exposed	19 / 1227 (1.55%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	19	1	0
Acne	Additional description: Acne		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Cafe au lait spots	Additional description: Cafe au lait spots		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic	Additional description: Dermatitis atopic		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Dermatitis diaper	Additional description: Dermatitis diaper		
subjects affected / exposed	0 / 1227 (0.00%)	2 / 1364 (0.15%)	0 / 1374 (0.00%)
occurrences (all)	0	2	0
Polymorphic eruption of pregnancy	Additional description: Polymorphic eruption of pregnancy		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Scar pain			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Swelling face			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Skin irritation			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Rosacea			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Petechiae			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1

Night sweats			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Keloid scar			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Ingrowing nail			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Erythema nodosum			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Proteinuria	Additional description: Proteinuria		
subjects affected / exposed	31 / 1227 (2.53%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	31	0	0
Bladder pain	Additional description: Bladder pain		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Dysuria	Additional description: Dysuria		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Pyelocaliectasis			

subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	0	1	0
Renal injury			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Urine odour abnormal			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Kidney enlargement			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Tachypnoea			
subjects affected / exposed	1 / 1227 (0.08%)	2 / 1364 (0.15%)	3 / 1374 (0.22%)
occurrences (all)	1	2	3
Renal tubular acidosis			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Renal pain			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Renal cyst			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Nephrotic syndrome			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Nephropathy			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Ketonuria			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Glycosuria			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Urinary hesitation			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Basedow's disease	Additional description: Basedow's disease		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	9 / 1227 (0.73%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	9	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia	Additional description: Arthralgia		
subjects affected / exposed	19 / 1227 (1.55%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	19	0	0
Back pain	Additional description: Back pain		
subjects affected / exposed	68 / 1227 (5.54%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	68	0	0
Muscle spasms	Additional description: Muscle spasms		
subjects affected / exposed	36 / 1227 (2.93%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	36	0	0
Myalgia	Additional description: Myalgia		
subjects affected / exposed	20 / 1227 (1.63%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	20	0	0
Musculoskeletal pain	Additional description: Musculoskeletal pain		

subjects affected / exposed	16 / 1227 (1.30%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	16	0	0
Pain in extremity	Additional description: Pain in extremity		
subjects affected / exposed	19 / 1227 (1.55%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	19	0	0
Symphysiolysis	Additional description: Symphysiolysis		
subjects affected / exposed	13 / 1227 (1.06%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	13	0	0
Bursitis	Additional description: Bursitis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Coccydynia	Additional description: Coccydynia		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Costochondritis	Additional description: Costochondritis		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Ligament pain	Additional description: Ligament pain		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Tenosynovitis stenosans			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	7	0	0
Systemic lupus erythematosus			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Polyarthrititis			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Pain in jaw			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Groin pain			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Infections and infestations			
Candidiasis	Additional description: Candidiasis		
subjects affected / exposed	9 / 1227 (0.73%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	9	1	0
Fungal infection	Additional description: Fungal infection		
subjects affected / exposed	16 / 1227 (1.30%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	16	0	0
Gastroenteritis viral	Additional description: Gastroenteritis viral		
subjects affected / exposed	34 / 1227 (2.77%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	34	0	0
Influenza	Additional description: Influenza		
subjects affected / exposed	16 / 1227 (1.30%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	16	0	0
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	24 / 1227 (1.96%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	24	1	0
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	80 / 1227 (6.52%)	2 / 1364 (0.15%)	1 / 1374 (0.07%)
occurrences (all)	80	2	1

Postoperative wound infection subjects affected / exposed occurrences (all)	Additional description: Postoperative wound infection		
	7 / 1227 (0.57%) 7	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	Additional description: Sinusitis		
	18 / 1227 (1.47%) 18	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Upper respiratory tract infection subjects affected / exposed occurrences (all)	Additional description: Upper respiratory tract infection		
	15 / 1227 (1.22%) 15	1 / 1364 (0.07%) 1	1 / 1374 (0.07%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	Additional description: Urinary tract infection		
	82 / 1227 (6.68%) 82	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Urinary tract infection, Wound infection subjects affected / exposed occurrences (all)	Additional description: Urinary tract infection, Wound infection		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abscess subjects affected / exposed occurrences (all)	Additional description: Abscess		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Abscess oral subjects affected / exposed occurrences (all)	Additional description: Abscess oral		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Acute sinusitis subjects affected / exposed occurrences (all)	Additional description: Acute sinusitis		
	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Croup infectious subjects affected / exposed occurrences (all)	Additional description: Croup infectious		
	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Cystitis subjects affected / exposed occurrences (all)	Additional description: Cystitis		
	9 / 1227 (0.73%) 9	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dacryocystitis subjects affected / exposed occurrences (all)	Additional description: Dacryocystitis		
	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Ear infection	Additional description: Ear infection		

subjects affected / exposed	10 / 1227 (0.81%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	10	0	1
Ureaplasma test positive	Additional description: Ureaplasma test positive		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Chikungunya virus infection	Additional description: Chikungunya virus infectiom		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Vulvovaginal mycotic infection	Additional description: Vulvovaginal mycotic infection		
subjects affected / exposed	5 / 1227 (0.41%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	5	0	0
Uterine infection	Additional description: Uterine infection		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Bacterial vaginosis	Additional description: Bacterial vaginosis		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Nail infection			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Lung infection			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Escherichia infection			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Staphylococcal infection			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Parvovirus infection			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Escherichia bacteraemia			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	0	0	1
Perineal abscess			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Febrile infection			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Haematoma infection			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Abscess limb			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Vaginal abscess			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Oral infection			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	6 / 1227 (0.49%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	6	0	0
Varicella			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Trichomoniasis			

subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Subcutaneous abscess			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Pilonidal cyst			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	4 / 1227 (0.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	4	0	0
Oral candidiasis			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	1	0	2
Omphalitis			
subjects affected / exposed	1 / 1227 (0.08%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	1	1	0
Lice infestation			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	12 / 1227 (0.98%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	12	0	0
Infected bite			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Hordeolum			

subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Herpes virus infection			
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Herpes simplex			
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Eye infection			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Impetigo			
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	5 / 1227 (0.41%)	9 / 1364 (0.66%)	14 / 1374 (1.02%)
occurrences (all)	5	9	14
Cow's milk intolerance	Additional description: Cow's milk intolerance		
subjects affected / exposed	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
occurrences (all)	0	1	1

Decreased appetite subjects affected / exposed occurrences (all)	4 / 1227 (0.33%) 4	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Metabolic disorder subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Decreased insulin requirement subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vitamin D deficiency subjects affected / exposed occurrences (all)	9 / 1227 (0.73%) 9	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vitamin B12 deficiency subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Metabolic acidosis subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Lactose intolerance subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Hyponatraemia subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Hypomagnesaemia subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Hypoglycaemia neonatal subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	5 / 1364 (0.37%) 5	6 / 1374 (0.44%) 6
Hypocalcaemia subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1

Hypercalcaemia subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Glucose tolerance impaired subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Feeding disorder neonatal subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	3 / 1364 (0.22%) 3	0 / 1374 (0.00%) 0
Electrolyte imbalance subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Increased insulin requirement subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0

Non-serious adverse events	placebo_mother		
Total subjects affected by non-serious adverse events subjects affected / exposed	930 / 1236 (75.24%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon	Additional description: Acrochordon		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Melanocytic naevus			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Gestational hypertension	Additional description: Gestational hypertension		
subjects affected / exposed	12 / 1236 (0.97%)		
occurrences (all)	12		
Hypertension	Additional description: Hypertension		
subjects affected / exposed	42 / 1236 (3.40%)		
occurrences (all)	42		
Subgaleal haematoma	Additional description: Subgaleal haematoma		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		

Hot flush			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Labile hypertension			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Thrombosis			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Thrombophlebitis superficial			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Thrombophlebitis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Orthostatic hypotension			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Labile blood pressure			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypovolaemic shock			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Haematoma			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Surgical and medical procedures			
Abortion induced	Additional description: Abortion induced		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Bartholin's cyst removal	Additional description: Bartholin's cyst removal		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
External cephalic version	Additional description: Failed external cephalic version		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Respiratory support	Additional description: Respiratory support		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Transfusion	Additional description: Transfusion		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Wound treatment			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Tooth extraction			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Office visit			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Ureteral stent insertion			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Surgery			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Tooth repair			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Physiotherapy			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
General anaesthesia			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Forceps delivery			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Episiotomy			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
Foetal growth restriction	Additional description: Foetal growth restriction		
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
Foetal hypokinesia	Additional description: Foetal hypokinesia		
subjects affected / exposed	92 / 1236 (7.44%)		
occurrences (all)	92		
Gestational diabetes	Additional description: Gestational diabetes		
subjects affected / exposed	90 / 1236 (7.28%)		
occurrences (all)	90		
Jaundice neonatal	Additional description: Jaundice neonatal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Polyhydramnios	Additional description: Polyhydramnios		
subjects affected / exposed	13 / 1236 (1.05%)		
occurrences (all)	13		
Postpartum haemorrhage	Additional description: Postpartum haemorrhage		
subjects affected / exposed	32 / 1236 (2.59%)		
occurrences (all)	32		
Pre-eclampsia	Additional description: Pre-eclampsia		
subjects affected / exposed	18 / 1236 (1.46%)		
occurrences (all)	18		
Premature baby	Additional description: Premature baby		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Premature rupture of membranes	Additional description: Premature rupture of membranes		

subjects affected / exposed	23 / 1236 (1.86%)		
occurrences (all)	23		
Uterine contractions during pregnancy	Additional description: Uterine contractions during pregnancy		
subjects affected / exposed	37 / 1236 (2.99%)		
occurrences (all)	37		
Born before arrival	Additional description: Born before arrival		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Contractions, Premature rupture of membranes	Additional description: Contractions, Premature rupture of membranes		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Contractions, Vaginal haemorrhage	Additional description: Contractions, Vaginal haemorrhage		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Contractions, Vaginal haemorrhage, Premature rupture of membranes	Additional description: Contractions, Vaginal haemorrhage, Premature rupture of membranes		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Low birth weight baby, Oligohydramnios	Additional description: Low birth weight baby, Oligohydramnios		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Placental transfusion syndrome, Oligohydramnios	Additional description: Placental transfusion syndrome, Oligohydramnios		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain lower, Contractions	Additional description: Abdominal pain lower, Contractions		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abortion threatened	Additional description: Abortion threatened		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Caesarean section	Additional description: Caesarean section		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Cephalhaematoma	Additional description: Cephalhaematoma		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Cervical incompetence	Additional description: Cervical incompetence		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Prenatal screening test abnormal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Low birth weight baby	Additional description: Low birth weight baby		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Amniorrhoea	Additional description: Amniorrhoea		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Placenta accreta	Additional description: Placenta accreta		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Labour pain			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Meconium stain			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Foetal macrosomia			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Labour induction			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Imminent abortion			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Meconium abnormal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vomiting in pregnancy			

subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Umbilical cord prolapse			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Retained placenta or membranes			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Placental disorder			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Placenta praevia			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Labour			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Large for dates baby			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Foetal distress syndrome			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Placental insufficiency			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
General disorders and administration site conditions			
Chest pain	Additional description: Chest pain		
subjects affected / exposed	22 / 1236 (1.78%)		
occurrences (all)	22		
Fatigue	Additional description: Fatigue		
subjects affected / exposed	37 / 1236 (2.99%)		
occurrences (all)	37		
Malaise	Additional description: Malaise		

subjects affected / exposed	18 / 1236 (1.46%)		
occurrences (all)	18		
Oedema	Additional description: Oedema		
subjects affected / exposed	38 / 1236 (3.07%)		
occurrences (all)	38		
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed	102 / 1236 (8.25%)		
occurrences (all)	102		
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed	7 / 1236 (0.57%)		
occurrences (all)	7		
Abdominal cramping, Vaginal discharge	Additional description: Abdominal cramping, Vaginal discharge		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal discomfort, Pelvic pain	Additional description: Abdominal discomfort, Pelvic pain		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Amniotic fluid leak	Additional description: Abdominal pain, Amniotic fluid leak		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Back pain	Additional description: Abdominal pain, Back pain		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Contractions	Additional description: Abdominal pain, Contractions		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Pyrexia	Additional description: Abdominal pain, Pyrexia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal pain, Vaginal discharge	Additional description: Abdominal pain, Vaginal discharge		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Vaginal haemorrhage	Additional description: Abdominal pain, Vaginal haemorrhage		

subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Abdominal pain lower, Back pain	Additional description: Abdominal pain lower, Back pain		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain lower, Vaginal haemorrhage, Back pain	Additional description: Abdominal pain lower, Vaginal haemorrhage, Back pain		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal pain upper, Dyspnoea	Additional description: Abdominal pain upper, Dyspnoea		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal pain upper, Headache	Additional description: Abdominal pain upper, Headache		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Abdominal pain upper, Nausea	Additional description: Abdominal pain upper, Nausea		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal pain upper, Headache, Oedema peripheral	Additional description: Abdominal pain upper, Headache, Oedema peripheral		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Abdominal pain, Diarrhoea, Back pain, Vaginal discharge	Additional description: Abdominal pain, Diarrhoea, Back pain, Vaginal discharge		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal pain, Back pain, Visual impairment	Additional description: Abdominal pain, Back pain, Visual impairment		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal pain, Headache, Oedema peripheral	Additional description: Abdominal pain, Headache, Oedema peripheral		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Malaise, Heart rate increased, Dehydration	Additional description: Abdominal pain, Malaise, Heart rate increased, Dehydration		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Vaginal	Additional description: Abdominal pain, Vaginal haemorrhage, Cholestasis of pregnancy		

haemorrhage, Cholestasis of pregnancy			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal pain, Vomiting, Tachypnoea	Additional description: Abdominal pain, Vomiting, Tachypnoea		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Back pain, Constipation	Additional description: Back pain, Constipation		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Back pain, Contractions	Additional description: Back pain, Contractions		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Back pain, Pollakiuria	Additional description: Back pain, Pollakiuria		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Back pain, Right sided pain, Vomiting	Additional description: Back pain, Right sided pain, Vomiting		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Back pain, Oropharyngeal pain, Diarrhoea, Pollakiuria	Additional description: Back pain, Oropharyngeal pain, Diarrhoea, Pollakiuria		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood glucose, Urine ketone body present	Additional description: Blood glucose and Urine ketone body present		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood glucose increased, Nausea	Additional description: Blood glucose increased, Nausea		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood pressure increased, Dyspnoea	Additional description: Blood pressure increased, Dyspnoea		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood pressure increased, Anogenital warts	Additional description: Blood pressure increased, Anogenital warts		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood pressure increased, Headache	Additional description: Blood pressure increased, Headache		

subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Blood pressure increased, Oedema peripheral	Additional description: Blood pressure increased, Oedema peripheral		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Blood pressure increased, Visual impairment	Additional description: Blood pressure increased, Visual impairment		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood pressure increased, Headache, Blurred vision	Additional description: Blood pressure increased, Headache, Blurred vision		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood pressure increased, Oedema	Additional description: Blood pressure increased, Oedema		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vision blurred, Dizziness, Protein urine	Additional description: Vision blurred, Dizziness, Protein urine		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Chest discomfort, Cough	Additional description: Chest discomfort, Cough		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Chorioamnionitis, Creatine urine increased	Additional description: Chorioamnionitis, Creatine urine increased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Constipation, Urinary tract infection, Vaginal discharge	Additional description: Constipation, Urinary tract infection, Vaginal discharge		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Contractions, Pelvic pain	Additional description: Contractions, Pelvic pain		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Contractions, Candida infection	Additional description: Contractions, Candida infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Contractions, Vomiting	Additional description: Contractions, Vomiting		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Diarrhoea, Nausea, Sensation of pressure, Vaginal discharge	Additional description: Diarrhoea, Nausea, Sensation of pressure, Vaginal discharge		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Dry eye, Dry mouth	Additional description: Dry eye, Dry mouth		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Dyspnoea, Asthenia, Vision blurred	Additional description: Dyspnoea, Asthenia, Vision blurred		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Dyspnoea, Diarrhoea, Myalgia, Abdominal pain, Back pain	Additional description: Dyspnoea, Diarrhoea, Myalgia, Abdominal pain, Back pain		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Dyspnoea, Headache, Oedema, Protein urine, Blood urine	Additional description: Dyspnoea, Headache, Oedema, Protein urine, Blood urine		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Dyspnoea, Chest pain	Additional description: Dyspnoea, Chest pain		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Fatigue, Abdominal pain, Nausea	Additional description: Fatigue, Abdominal pain, Nausea		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Fatigue, Oropharyngeal pain, Abdominal pain upper	Additional description: Fatigue, Oropharyngeal pain, Abdominal pain upper		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Amylase increased	Additional description: Headache, Amylase increased		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Arthralgia	Additional description: Headache, Arthralgia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Back pain	Additional description: Headache, Back pain		

subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Headache, Diarrhoea	Additional description: Headache, Diarrhoea		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Oedema			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Oedema peripheral	Additional description: Headache, Oedema peripheral		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Pain in extremity	Additional description: Headache, Pain in extremity		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Protein urine	Additional description: Headache, Protein urine		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Proteinuria	Additional description: Headache, Proteinuria		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Urine protein/creatinine ratio	Additional description: Headache, Urine protein/creatinine ratio		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Dizziness, Night sweats	Additional description: Headache, Dizziness, Night sweats		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Ear pain, Nausea, Dyspepsia	Additional description: Headache, Ear pain, Nausea, Dyspepsia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Pain in extremity, Diarrhoea	Additional description: Headache, Pain in extremity, Diarrhoea		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Nausea, Back pain	Additional description: Headache, Nausea, Back pain		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Oedema, Visual impairment			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Oedema peripheral, Visual impairment, Abdominal pain upper, Dyspepsia	Additional description: Headache, Oedema peripheral, Visual impairment, Abdominal pain upper, Dyspepsia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Oedema, Abdominal pain, Hypertension	Additional description: Headache, Oedema, Abdominal pain, Hypertension		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Oedema, Abdominal pain upper, Malaise	Additional description: Headache, Oedema, Abdominal pain upper, Malaise		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Oedema, Blood pressure increased, Protein urine	Additional description: Headache, Oedema, Blood pressure increased, Protein urine		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Headache, Dysuria, Candida infection	Additional description: Headache, Dysuria, Candida infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Visual impairment, Nausea, Diarrhoea	Additional description: Headache, Visual impairment, Nausea, Diarrhoea		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Headache, Vomiting, Hypertension	Additional description: Headache, Vomiting, Hypertension		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hypertension, Oedema peripheral	Additional description: Hypertension, Oedema peripheral		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hypertension, Proteinuria	Additional description: Hypertension, Proteinuria		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Hypertension, Heart rate increased, Palpitations	Additional description: Hypertension, Heart rate increased, Palpitations	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	
Pain in extremity, Oedema peripheral, Haemoptysis	Additional description: Pain in extremity, Oedema peripheral, Haemoptysis	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Lethargy, Dizziness, Dyspepsia	Additional description: Lethargy, Dizziness, Dyspepsia	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	
Loss of consciousness, Foetal hypokinesia	Additional description: Loss of consciousness, Foetal hypokinesia	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Malaise, Oedema peripheral	Additional description: Malaise, Oedema peripheral	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	
Maternal exposure during pregnancy to Varicella	Additional description: Maternal exposure during pregnancy to Varicella	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Migraine, Syncope, Bell's palsy	Additional description: Migraine, Syncope, Bell's palsy	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Musculoskeletal pain, Urinary tract infection, Dyspepsia	Additional description: Musculoskeletal pain, Urinary tract infection, Dyspepsia	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Myalgia, Vaginal discharge	Additional description: Myalgia, Vaginal discharge	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	
Nausea, Palpitations, Insomnia	Additional description: Nausea, Palpitations, Insomnia	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Jaundice neonatal, Hypoglycaemia neonatal, Sepsis neonatal	Additional description: Jaundice neonatal, Hypoglycaemia neonatal, Sepsis neonatal	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	

Oedema peripheral, Dizziness subjects affected / exposed occurrences (all)	Additional description: Oedema peripheral, Dizziness	
	1 / 1236 (0.08%) 1	
Oedema peripheral, Candida infection subjects affected / exposed occurrences (all)	Additional description: Oedema peripheral, Candida infection	
	0 / 1236 (0.00%) 0	
Oedema peripheral, Vulvovaginal swelling subjects affected / exposed occurrences (all)	Additional description: Oedema peripheral, Vulvovaginal swelling	
	0 / 1236 (0.00%) 0	
Pain in extremity, Vaginal haemorrhage, Abdominal pain subjects affected / exposed occurrences (all)	Additional description: Pain in extremity, Vaginal haemorrhage, Abdominal pain	
	1 / 1236 (0.08%) 1	
Premature rupture of membranes, Chorioamnionitis subjects affected / exposed occurrences (all)	Additional description: Premature rupture of membranes, Chorioamnionitis	
	0 / 1236 (0.00%) 0	
Premature rupture of membranes, Vaginal haemorrhage subjects affected / exposed occurrences (all)	Additional description: Premature rupture of membranes, Vaginal haemorrhage	
	1 / 1236 (0.08%) 1	
Protein urine, Oedema peripheral subjects affected / exposed occurrences (all)	Additional description: Protein urine, Oedema peripheral	
	1 / 1236 (0.08%) 1	
Proteinuria, Oedema peripheral subjects affected / exposed occurrences (all)	Additional description: Proteinuria, Oedema peripheral	
	0 / 1236 (0.00%) 0	
Pruritus, Back pain, Oedema subjects affected / exposed occurrences (all)	Additional description: Pruritus, Back pain, Oedema	
	0 / 1236 (0.00%) 0	
Rash, Foetal hypokinesia subjects affected / exposed occurrences (all)	Additional description: Rash, Foetal hypokinesia	
	0 / 1236 (0.00%) 0	
Rash, Pyrexia subjects affected / exposed occurrences (all)	Additional description: Rash, Pyrexia	
	0 / 1236 (0.00%) 0	
Reflux gastritis, Ketone body in urine	Additional description: Reflux gastritis, Ketone body in urine	

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Sciatica, Skin infection	Additional description: Sciatica, Skin infection		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Shoulder dystocia, Erb's palsy	Additional description: Shoulder dystocia, Erb's palsy		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Musculoskeletal pain, Rash	Additional description: Shoulder pain, Rash		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Thirst, Hyperhidrosis	Additional description: Thirst, Hyperhidrosis		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vaginal discomfort, Back pain, Dysuria	Additional description: Vaginal discomfort, Back pain, Dysuria		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage, Pain	Additional description: Vaginal haemorrhage, Pain		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage, Pelvic pain	Additional description: Vaginal haemorrhage, Pelvic pain		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage, Vaginal discharge	Additional description: Vaginal haemorrhage, Vaginal discharge		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage, Diarrhoea, Incontinence	Additional description: Vaginal haemorrhage, Diarrhoea, Incontinence		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Visual impairment, Dyspnoea, Polyhydramnios	Additional description: Visual impairment, Dyspnoea, Polyhydramnios		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vomiting, Dizziness, Migraine	Additional description: Vomiting, Dizziness, Migraine		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abdominal pain, Back pain, Vaginal discharge	Additional description: Abdominal pain, Back pain, Vaginal discharge		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Asthenia	Additional description: Asthenia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Chest discomfort	Additional description: Chest discomfort		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Drug level changed			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Fat necrosis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
General symptom			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Injection site nodule			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Thirst			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Swelling			
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
Sensation of pressure			
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Pre-existing condition improved			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Pain			
subjects affected / exposed	6 / 1236 (0.49%)		
occurrences (all)	6		
Irritability			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Impaired healing			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hypothermia neonatal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Feeling abnormal			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Face oedema			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Feeling hot			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Immune system disorders			
ABO incompatibility	Additional description: ABO incompatibility		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Drug hypersensitivity	Additional description: Drug hypersensitivity		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
House dust allergy			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Seasonal allergy			
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Food allergy			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Pelvic pain	Additional description: Pelvic pain		
subjects affected / exposed	31 / 1236 (2.51%)		
occurrences (all)	31		
Vaginal discharge	Additional description: Vaginal discharge		
subjects affected / exposed	18 / 1236 (1.46%)		
occurrences (all)	18		
Vaginal haemorrhage	Additional description: Vaginal haemorrhage		
subjects affected / exposed	61 / 1236 (4.94%)		
occurrences (all)	61		
Bartholinitis	Additional description: Bartholinitis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Breast cyst	Additional description: Breast cyst		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Breast pain	Additional description: Breast pain		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Breast tenderness	Additional description: Breast tenderness		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Cervix disorder	Additional description: Cervix disorder		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vulvovaginal pain	Additional description: Vulvovaginal pain		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Vulvovaginal burning sensation	Additional description: Vulvovaginal burning sensation		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Coital bleeding	Additional description: Coital bleeding		

subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed	7 / 1236 (0.57%)		
occurrences (all)	7		
Uterine cervical pain			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vulvovaginal pruritus			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Cervical friability			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Cervix haematoma uterine			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vaginal lesion			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vulvovaginal discomfort			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Varicose veins vulval			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vaginal odour			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vaginal laceration			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Uterine spasm			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Uterine atony			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Uterine haemorrhage			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough	Additional description: Cough		
subjects affected / exposed	26 / 1236 (2.10%)		
occurrences (all)	26		
Dyspnoea	Additional description: Dyspnoea		
subjects affected / exposed	86 / 1236 (6.96%)		
occurrences (all)	86		
Epistaxis	Additional description: Epistaxis		
subjects affected / exposed	22 / 1236 (1.78%)		
occurrences (all)	22		
Oropharyngeal pain	Additional description: Oropharyngeal pain		
subjects affected / exposed	13 / 1236 (1.05%)		
occurrences (all)	13		
Atelectasis, Pneumothorax	Additional description: Atelectasis, Pneumothorax		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Bronchospasm	Additional description: Bronchospasm		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Chronic obstructive pulmonary disease	Additional description: Chronic obstructive pulmonary disease		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Dyspnoea exertional	Additional description: Dyspnoea exertional		
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Wheezing			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Transient tachypnoea of the newborn			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Sleep apnoea syndrome			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Sinus congestion			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Productive cough			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	12 / 1236 (0.97%)		
occurrences (all)	12		
Pulmonary haemorrhage neonatal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia	Additional description: Insomnia		
subjects affected / exposed	17 / 1236 (1.38%)		
occurrences (all)	17		
Anxiety	Additional description: Anxiety		
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
Anxiety attack	Additional description: Anxiety attack		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Breath holding subjects affected / exposed occurrences (all)	Additional description: Breath holding	
	0 / 1236 (0.00%) 0	
Depressed mood subjects affected / exposed occurrences (all)	Additional description: Depressed mood	
	1 / 1236 (0.08%) 1	
Depression subjects affected / exposed occurrences (all)	Additional description: Depression	
	2 / 1236 (0.16%) 2	
Disturbance in attention subjects affected / exposed occurrences (all)	Additional description: Disturbance in attention	
	1 / 1236 (0.08%) 1	
Postpartum depression subjects affected / exposed occurrences (all)		
	4 / 1236 (0.32%) 4	
Sleep disorder subjects affected / exposed occurrences (all)		
	2 / 1236 (0.16%) 2	
Panic attack subjects affected / exposed occurrences (all)		
	2 / 1236 (0.16%) 2	
Nervousness subjects affected / exposed occurrences (all)		
	1 / 1236 (0.08%) 1	
Mood swings subjects affected / exposed occurrences (all)		
	2 / 1236 (0.16%) 2	
Hepatobiliary disorders		
Hyperbilirubinaemia neonatal subjects affected / exposed occurrences (all)	Additional description: Hyperbilirubinaemia neonatal	
	0 / 1236 (0.00%) 0	
Cholecystitis subjects affected / exposed occurrences (all)	Additional description: Cholecystitis	
	2 / 1236 (0.16%) 2	
Hepatomegaly		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hepatic pain			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Investigations			
Blood pressure increased	Additional description: Blood pressure increased		
subjects affected / exposed	40 / 1236 (3.24%)		
occurrences (all)	40		
Protein urine present	Additional description: Protein urine present		
subjects affected / exposed	13 / 1236 (1.05%)		
occurrences (all)	13		
Serum ferritin	Additional description: Serum ferritin		
subjects affected / exposed	7 / 1236 (0.57%)		
occurrences (all)	7		
Blood pressure increased, Protein in urine	Additional description: Blood pressure increased, Protein in urine		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood pressure increased, Proteinuria	Additional description: Blood pressure increased, Proteinuria		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Alanine aminotransferase increased	Additional description: Alanine aminotransferase increased		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Albumin urine	Additional description: Albumin urine test		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased	Additional description: Aspartate aminotransferase increased		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Blood bicarbonate	Additional description: Blood bicarbonate		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood bilirubin	Additional description: Blood bilirubin		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood calcium	Additional description: Blood calcium		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood chloride	Additional description: Blood chloride		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Blood creatine	Additional description: Blood creatine		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood fibrinogen increased	Additional description: Blood fibrinogen increased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood gases abnormal	Additional description: Blood gases abnormal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood iron decreased	Additional description: Blood iron decreased		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase	Additional description: Blood lactate dehydrogenase		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood potassium decreased	Additional description: Blood potassium decreased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood pressure abnormal	Additional description: Blood pressure abnormal		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood pressure decreased	Additional description: Blood pressure decreased		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Blood sodium	Additional description: Blood sodium		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood sodium abnormal	Additional description: Blood sodium abnormal		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood thyroid stimulating hormone	Additional description: Blood thyroid stimulating hormone		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Blood urea	Additional description: Blood urea		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood uric acid increased	Additional description: Blood uric acid increased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Blood urine	Additional description: Blood urine		
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Human rhinovirus test positive	Additional description: Human rhinovirus test positive		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Streptococcus test positive	Additional description: Streptococcus test positive		
subjects affected / exposed	8 / 1236 (0.65%)		
occurrences (all)	8		
Respiratory syncytial virus test positive	Additional description: Respiratory syncytial virus test positive		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Venous oxygen partial pressure decreased	Additional description: Venous oxygen partial pressure decreased		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Total bile acids increased	Additional description: Total bile acids increased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Fibronectin increased	Additional description: Fibronectin increased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Amniotic fluid volume increased	Additional description: Amniotic fluid volume increased		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Amniotic fluid volume decreased	Additional description: Amniotic fluid volume decreased		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Urine cannabinoids increased			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Urine analysis abnormal			
subjects affected / exposed	9 / 1236 (0.73%)		
occurrences (all)	9		
Hepatic enzyme increased			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Gastric pH decreased			
subjects affected / exposed	9 / 1236 (0.73%)		
occurrences (all)	9		
Total bile acids			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Base excess			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Urine ketone body present			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Urine protein/creatinine ratio increased			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Urine albumin/creatinine ratio increased			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Foetal heart rate abnormal			

subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Urine leukocyte esterase positive			
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
White blood cell count decreased			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vitamin B12			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Tri-iodothyronine			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Serum ferritin decreased			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Platelet count			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Physical examination			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Oxygen saturation decreased			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Heart rate increased			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Heart rate abnormal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Haemoglobin			

subjects affected / exposed	11 / 1236 (0.89%)		
occurrences (all)	11		
Haemoglobin decreased			
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
Haematocrit			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Glycosylated haemoglobin			
subjects affected / exposed	7 / 1236 (0.57%)		
occurrences (all)	7		
Glucose urine present			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Glucose urine			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Glucose tolerance test			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Fall	Additional description: Fall		
subjects affected / exposed	13 / 1236 (1.05%)		
occurrences (all)	13		
Accidental overdose	Additional description: Accidental overdose		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Accidental poisoning	Additional description: Accidental poisoning		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Animal bite	Additional description: Animal bite (dog)		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Ankle fracture	Additional description: Ankle fracture		

subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Clavicle fracture	Additional description: Clavicle fracture		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Maternal exposure during pregnancy to Hand-foot-and-mouth disease	Additional description: Maternal exposure during pregnancy to Hand-foot-and-mouth disease		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Foreign body	Additional description: Foreign body		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Skeletal injury			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Limb injury			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Procedural complication			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Thermal burn			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Contusion			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Muscle strain			
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Excoriation			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Uterine rupture			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Sunburn			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Seroma			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Road traffic accident			
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
Perineal laceration			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Foot fracture			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Femoral nerve injury			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital, familial and genetic disorders			
Congenital cardiovascular anomaly	Additional description: Congenital cardiovascular anomaly		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Apert's syndrome	Additional description: Apert's syndrome		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Atrial septal defect	Additional description: Atrial septal defect		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Cataract congenital	Additional description: Cataract congenital		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital anomaly	Additional description: Congenital anomaly		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital central nervous system anomaly			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Cryptorchism			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Developmental hip dysplasia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital skin dimples			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Skeletal dysplasia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital naevus			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Naevus flammeus			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Ectopic kidney			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Skull malformation			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Anomaly of external ear congenital			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital Eustachian tube anomaly			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Congenital oral malformation subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Laryngomalacia subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Trisomy 18 subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Congenital eye naevus subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Congenital hydronephrosis subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Macrocephaly subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Congenital adrenal gland hypoplasia subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Trisomy 21 subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Talipes subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Sebaceous naevus subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Pyloric stenosis subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Pulmonary malformation subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		

Pulmonary artery stenosis congenital			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Patent ductus arteriosus			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Limb malformation			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Kidney duplex			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypospadias			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hydrocele			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Heart disease congenital			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Haemangioma congenital			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Gastroschisis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Galactosaemia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Exomphalos			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Congenital hypothyroidism			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		

Cardiac disorders			
Palpitations	Additional description: Palpitations		
subjects affected / exposed	15 / 1236 (1.21%)		
occurrences (all)	15		
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Bradycardia foetal	Additional description: Bradycardia foetal		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Bundle branch block left	Additional description: Bundle branch block left		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Cardiomegaly	Additional description: Cardiomegaly		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Cyanosis	Additional description: Cyanosis		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Foetal heart rate deceleration abnormality			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Bradycardia neonatal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pericardial cyst			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Tachycardia foetal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pericarditis			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Pericardial effusion			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Klinefelter's syndrome			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Extrasystoles			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Carpal tunnel syndrome	Additional description: Carpal tunnel syndrome		
subjects affected / exposed	17 / 1236 (1.38%)		
occurrences (all)	17		
Dizziness	Additional description: Dizziness		
subjects affected / exposed	44 / 1236 (3.56%)		
occurrences (all)	44		
Headache	Additional description: Headache		
subjects affected / exposed	302 / 1236 (24.43%)		
occurrences (all)	302		
Hypoaesthesia	Additional description: Hypoaesthesia		

subjects affected / exposed	13 / 1236 (1.05%)		
occurrences (all)	13		
Migraine	Additional description: Migraine		
subjects affected / exposed	22 / 1236 (1.78%)		
occurrences (all)	22		
Sciatica	Additional description: Sciatica		
subjects affected / exposed	18 / 1236 (1.46%)		
occurrences (all)	18		
Aphasia	Additional description: Aphasia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Apraxia	Additional description: Apraxia		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Burning sensation	Additional description: Burning sensation		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Convulsion	Additional description: Convulsion		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Depressed level of consciousness	Additional description: Depressed level of consciousness		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hyperglycaemic seizure	Additional description: Hyperglycaemic seizure		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Restless legs syndrome			
subjects affected / exposed	6 / 1236 (0.49%)		
occurrences (all)	6		
VIIth nerve paralysis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
VIth nerve paralysis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Tremor			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Tension headache			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	6 / 1236 (0.49%)		
occurrences (all)	6		
Somnolence			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Sinus headache			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	6 / 1236 (0.49%)		
occurrences (all)	6		
Paraesthesia			
subjects affected / exposed	8 / 1236 (0.65%)		
occurrences (all)	8		
Nerve compression			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Migraine with aura			
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Loss of consciousness			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Lethargy			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypotonic-hyporesponsive episode			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			

<p>Anaemia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Splenic cyst</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Thrombocytopenia neonatal</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Thrombocytopenia</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Lymphadenopathy</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	Additional description: Anaemia		
	54 / 1236 (4.37%)		
	54		
	0 / 1236 (0.00%)		
	0		
	0 / 1236 (0.00%)		
<p>Ear and labyrinth disorders</p> <p>Acoustic stimulation tests abnormal</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Deafness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Ear pain</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Ear discomfort</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Tinnitus</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	Additional description: Acoustic stimulation tests abnormal		
	0 / 1236 (0.00%)		
	0		
	Additional description: Deafness		
	1 / 1236 (0.08%)		
	1		
<p>Eye disorders</p> <p>Conjunctivitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Vision Blurred</p>	Additional description: Ear pain		
	7 / 1236 (0.57%)		
	7		
	1 / 1236 (0.08%)		
	1		
	2 / 1236 (0.16%)		
<p>Conjunctivitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	Additional description: Vision Blurred		
	13 / 1236 (1.05%)		
	13		
Additional description: Vision Blurred			

subjects affected / exposed	19 / 1236 (1.54%)		
occurrences (all)	19		
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed	61 / 1236 (4.94%)		
occurrences (all)	61		
Diabetic retinopathy	Additional description: Diabetic retinopathy		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Dry eye	Additional description: Dry eye		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Sunset eyes	Additional description: Sunset Eyes/ Setting sun phenomenon		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Chorioretinopathy	Additional description: Chorioretinopathy		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vitreous floaters			
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Visual field defect			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Scintillating scotoma			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Photopsia			
subjects affected / exposed	7 / 1236 (0.57%)		
occurrences (all)	7		
Photophobia			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Periorbital oedema			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Eye pain			

subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed	20 / 1236 (1.62%)		
occurrences (all)	20		
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed	58 / 1236 (4.69%)		
occurrences (all)	58		
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed	64 / 1236 (5.18%)		
occurrences (all)	64		
Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	34 / 1236 (2.75%)		
occurrences (all)	34		
Constipation	Additional description: Constipation		
subjects affected / exposed	53 / 1236 (4.29%)		
occurrences (all)	53		
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	136 / 1236 (11.00%)		
occurrences (all)	136		
Gastrooesophageal reflux disease	Additional description: Gastrooesophageal reflux disease		
subjects affected / exposed	54 / 1236 (4.37%)		
occurrences (all)	54		
Nausea	Additional description: Nausea		
subjects affected / exposed	96 / 1236 (7.77%)		
occurrences (all)	96		
Toothache	Additional description: Toothache		
subjects affected / exposed	14 / 1236 (1.13%)		
occurrences (all)	14		
Vomiting	Additional description: Vomiting		
subjects affected / exposed	85 / 1236 (6.88%)		
occurrences (all)	85		
Abdominal pain, Nausea	Additional description: Abdominal pain, Nausea		

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Constipation, Dyspepsia	Additional description: Constipation, Dyspepsia		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Gastrointestinal inflammation	Additional description: Gastrointestinal inflammation		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Tooth abscess			
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Retching			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Rectal haemorrhage			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Proctitis			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Periodontal disease			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Oesophageal spasm			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Mouth ulceration			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Lip swelling			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Intestinal dilatation			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Infantile colic			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	9 / 1236 (0.73%)		
occurrences (all)	9		
Haematemesis			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Gingivitis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Gingival swelling			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Gingival bleeding			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Gastrointestinal disorder			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Gastritis			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Frequent bowel movements			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Food poisoning			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Flatulence			

subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Flank pain			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Oral pain			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Pruritus	Additional description: Pruritus		
subjects affected / exposed	41 / 1236 (3.32%)		
occurrences (all)	41		
Rash	Additional description: Rash		
subjects affected / exposed	11 / 1236 (0.89%)		
occurrences (all)	11		
Acne	Additional description: Acne		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Cafe au lait spots	Additional description: Cafe au lait spots		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Dermatitis atopic	Additional description: Dermatitis atopic		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Dermatitis diaper	Additional description: Dermatitis diaper		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Polymorphic eruption of pregnancy	Additional description: Polymorphic eruption of pregnancy		
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
Scar pain			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Swelling face			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		

Skin irritation			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Rosacea			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Rash pruritic			
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		
Petechiae			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Keloid scar			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Ingrowing nail			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hyperhidrosis			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Hypersensitivity			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Erythema			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Erythema nodosum			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Renal and urinary disorders			
Proteinuria	Additional description: Proteinuria		
subjects affected / exposed	28 / 1236 (2.27%)		
occurrences (all)	28		
Bladder pain	Additional description: Bladder pain		
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Dysuria	Additional description: Dysuria		
subjects affected / exposed	6 / 1236 (0.49%)		
occurrences (all)	6		
Pyelocaliectasis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Renal injury			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Urine odour abnormal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Kidney enlargement			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Tachypnoea			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Renal tubular acidosis			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Renal pain			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Renal cyst			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pollakiuria			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Nephrotic syndrome			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Nephropathy			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Micturition urgency			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Ketonuria			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Haematuria			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Glycosuria			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Urinary hesitation			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Endocrine disorders			
Basedow's disease	Additional description: Basedow's disease		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypothyroidism			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Hyperthyroidism			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			

Arthralgia	Additional description: Arthralgia	
subjects affected / exposed	20 / 1236 (1.62%)	
occurrences (all)	20	
Back pain	Additional description: Back pain	
subjects affected / exposed	74 / 1236 (5.99%)	
occurrences (all)	74	
Muscle spasms	Additional description: Muscle spasms	
subjects affected / exposed	35 / 1236 (2.83%)	
occurrences (all)	35	
Myalgia	Additional description: Myalgia	
subjects affected / exposed	10 / 1236 (0.81%)	
occurrences (all)	10	
Musculoskeletal pain	Additional description: Musculoskeletal pain	
subjects affected / exposed	14 / 1236 (1.13%)	
occurrences (all)	14	
Pain in extremity	Additional description: Pain in extremity	
subjects affected / exposed	19 / 1236 (1.54%)	
occurrences (all)	19	
Symphysiolysis	Additional description: Symphysiolysis	
subjects affected / exposed	23 / 1236 (1.86%)	
occurrences (all)	23	
Bursitis	Additional description: Bursitis	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Coccydynia	Additional description: Coccydynia	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Costochondritis	Additional description: Costochondritis	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Ligament pain	Additional description: Ligament pain	
subjects affected / exposed	6 / 1236 (0.49%)	
occurrences (all)	6	
Tenosynovitis stenosans		
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	

Musculoskeletal stiffness subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	11 / 1236 (0.89%) 11		
Systemic lupus erythematosus subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Psoriatic arthropathy subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Polyarthrititis subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Plantar fasciitis subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Pain in jaw subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Neck pain subjects affected / exposed occurrences (all)	3 / 1236 (0.24%) 3		
Joint stiffness subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Groin pain subjects affected / exposed occurrences (all)	7 / 1236 (0.57%) 7		
Infections and infestations			
Candidiasis	Additional description: Candidiasis		
subjects affected / exposed	17 / 1236 (1.38%)		
occurrences (all)	17		
Fungal infection	Additional description: Fungal infection		

subjects affected / exposed	10 / 1236 (0.81%)		
occurrences (all)	10		
Gastroenteritis viral	Additional description: Gastroenteritis viral		
subjects affected / exposed	35 / 1236 (2.83%)		
occurrences (all)	35		
Influenza	Additional description: Influenza		
subjects affected / exposed	29 / 1236 (2.35%)		
occurrences (all)	29		
Lower respiratory tract infection	Additional description: Lower respiratory tract infection		
subjects affected / exposed	16 / 1236 (1.29%)		
occurrences (all)	16		
Nasopharyngitis	Additional description: Nasopharyngitis		
subjects affected / exposed	85 / 1236 (6.88%)		
occurrences (all)	85		
Postoperative wound infection	Additional description: Postoperative wound infection		
subjects affected / exposed	14 / 1236 (1.13%)		
occurrences (all)	14		
Sinusitis	Additional description: Sinusitis		
subjects affected / exposed	18 / 1236 (1.46%)		
occurrences (all)	18		
Upper respiratory tract infection	Additional description: Upper respiratory tract infection		
subjects affected / exposed	23 / 1236 (1.86%)		
occurrences (all)	23		
Urinary tract infection	Additional description: Urinary tract infection		
subjects affected / exposed	89 / 1236 (7.20%)		
occurrences (all)	89		
Urinary tract infection, Wound infection	Additional description: Urinary tract infection, Wound infection		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abscess	Additional description: Abscess		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Abscess oral	Additional description: Abscess oral		
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Acute sinusitis	Additional description: Acute sinusitis	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Croup infectious	Additional description: Croup infectious	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Cystitis	Additional description: Cystitis	
subjects affected / exposed	2 / 1236 (0.16%)	
occurrences (all)	2	
Dacryocystitis	Additional description: Dacryocystitis	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Ear infection	Additional description: Ear infection	
subjects affected / exposed	6 / 1236 (0.49%)	
occurrences (all)	6	
Ureaplasma test positive	Additional description: Ureaplasma test positive	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Chikungunya virus infection	Additional description: Chikungunya virus infection	
subjects affected / exposed	3 / 1236 (0.24%)	
occurrences (all)	3	
Oral herpes	Additional description: Oral herpes	
subjects affected / exposed	2 / 1236 (0.16%)	
occurrences (all)	2	
Vulvovaginal mycotic infection	Additional description: Vulvovaginal mycotic infection	
subjects affected / exposed	3 / 1236 (0.24%)	
occurrences (all)	3	
Uterine infection	Additional description: Uterine infection	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	
Bacterial vaginosis	Additional description: Bacterial vaginosis	
subjects affected / exposed	6 / 1236 (0.49%)	
occurrences (all)	6	
Nail infection		
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	

Lung infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Escherichia infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Staphylococcal infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Parvovirus infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Escherichia bacteraemia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Perineal abscess			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Escherichia urinary tract infection			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Febrile infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Haematoma infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Abscess limb			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Vaginal abscess			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	5 / 1236 (0.40%)		
occurrences (all)	5		

Oral infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vulvovaginal candidiasis			
subjects affected / exposed	9 / 1236 (0.73%)		
occurrences (all)	9		
Varicella			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vaginal infection			
subjects affected / exposed	6 / 1236 (0.49%)		
occurrences (all)	6		
Trichomoniasis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Subcutaneous abscess			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Skin infection			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pilonidal cyst			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Oral candidiasis			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		

Omphalitis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Lice infestation			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Influenza like illness			
subjects affected / exposed	8 / 1236 (0.65%)		
occurrences (all)	8		
Infected bite			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hordeolum			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	2 / 1236 (0.16%)		
occurrences (all)	2		
Herpes virus infection			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Herpes simplex			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Furuncle			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Folliculitis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Eye infection			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		

Impetigo			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Laryngitis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Cow's milk intolerance	Additional description: Cow's milk intolerance		
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	3 / 1236 (0.24%)		
occurrences (all)	3		
Metabolic disorder			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Decreased insulin requirement			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Vitamin D deficiency			
subjects affected / exposed	8 / 1236 (0.65%)		
occurrences (all)	8		
Vitamin B12 deficiency			
subjects affected / exposed	4 / 1236 (0.32%)		
occurrences (all)	4		
Metabolic acidosis			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Lactose intolerance			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hyponatraemia			

subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypomagnesaemia			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hypokalaemia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypoglycaemia neonatal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Hypercalcaemia			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Glucose tolerance impaired			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Feeding disorder neonatal			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Electrolyte imbalance			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Increased insulin requirement			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 March 2011	The following Inclusion Criteria was removed: Subject's primary obstetrical care provider agrees with subject's participation in the study. Rational: The Qualified Investigator will decide on the Participant's eligibility. If the Participant is agreeable, the primary obstetrical provider will be notified of the Participant's study involvement.
20 July 2011	The subject will be provided with written instructions on how to take the Study Treatment. Rational: Current labels do not include instructions on how to take Study Treatment. Instructions are presently on the Participant Diary. The Participant Diary, which is given to the Participant at each study visit, includes detailed, written instructions on how to take the Study Treatment. Participants will also be given verbal instructions at each study visit. Furthermore, over-labelling to ensure regulatory compliance in other participating countries is required.
15 December 2011	Subject is taking ≤ 1 mg of folic acid daily at the time of randomization and amended protocol so allowable amount of folic acid intake to be ≤ 1.1 mg of folic acid daily at the time of randomization. Rationale: 1.1 mg of Folic Acid may be prescribed as standard of care in many participating hospitals. The additional 0.1 mg may inhibit Participant recruitment. It was decided to increase the folic acid amounts from ≤ 1 mg to ≤ 1.1 mg. The additional 0.1 mg poses no safety concerns and does not affect the methodology of the Trial.
18 March 2013	Amendment to include confirmation of fetal/embryonic viability* prior to subject randomization Rationale: Define the physical examination requirements for Visit 1. After confirmation of fetal/embryonic cardiac activity post 8 weeks of gestation, in the absence of significant vaginal bleeding, the risk of miscarriage is significantly reduced, and the requirement for re-confirmation of viability is not required.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/30209050>