

**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.

Baseline characteristics

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

Variability estimate	Standard deviation
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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, Polyhydraminos	Additional description: Shortened cervix, Polyhydraminos		
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	Additional description: Threatened labour, Cystitis		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Unstable foetal lie, Polyhydraminos subjects affected / exposed	Additional description: Unstable foetal lie, Polyhydraminos		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Weight loss, Hypernatraemia subjects affected / exposed	Additional description: Weight loss, Hypernatraemia		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
	0 / 0	0 / 1	0 / 1
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Immune system disorders Anaphylactic reaction subjects affected / exposed	Additional description: Anaphylactic reaction		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Milk allergy subjects affected / exposed	Additional description: Milk allergy		
	0 / 1227 (0.00%)	1 / 1364 (0.07%)	1 / 1374 (0.07%)
	0 / 0	0 / 1	0 / 1
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders Cervical polyp subjects affected / exposed	Additional description: Cervical polyp		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Scrotal mass subjects affected / exposed	Additional description: Scrotal mass		
	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	0 / 0	0 / 0	0 / 1
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
	0 / 0	0 / 0	0 / 0
	0 / 0	0 / 0	0 / 0
Shortened cervix subjects affected / exposed	Additional description: Shortened cervix		
	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 2	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
	0 / 0	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	Additional description: Blood glucose decreased		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	0 / 1	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
	Additional description: Blood glucose increased		
	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
Blood glucose increased subjects affected / exposed	0 / 1	0 / 0	0 / 0
	Additional description: Blood pressure increased		
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	Additional description: Blood pressure increased, Proteinuria		
	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	Additional description: Cardiac murmur		
	0 / 2	0 / 0	0 / 0
Blood pressure increased, Proteinuria subjects affected / exposed	0 / 0	0 / 0	0 / 0
	Additional description: Foetal monitoring abnormal		
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 1227 (0.00%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
	Additional description: Foetal non-stress test abnormal		
	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
Foetal monitoring abnormal subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	Additional description: Ultrasound Doppler abnormal		
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
Glucose tolerance test abnormal subjects affected / exposed	0 / 1	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
Ultrasound Doppler abnormal subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
Ultrasound Doppler abnormal subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
	Additional description: Glucose tolerance test abnormal		
	0 / 0	0 / 0	0 / 0

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	Additional description: Ankyloglossia congenital		
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	Additional description: Acute fatty liver of pregnancy		
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				
	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
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%)	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
Musculoskeletal pain	Additional description: Musculoskeletal pain			
	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
Pain in extremity	Additional description: 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
Pubic pain	Additional description: Pubic pain			
	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
Infections and infestations	Additional description: Appendicitis			
	Appendicitis			
	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
Arthritis bacterial	Additional description: Arthritis bacterial			
	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
Bronchiolitis	Additional description: Bronchiolitis			
	subjects affected / exposed	1 / 1227 (0.08%)	2 / 1364 (0.15%)	2 / 1374 (0.15%)
	occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
	deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis	Additional description: Bronchitis			
	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
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	Additional description: Failed induction of labour	
	1 / 1236 (0.08%)	
	0 / 1	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
False labour subjects affected / exposed	Additional description: False labour	
	0 / 1236 (0.00%)	
	0 / 0	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Foetal death subjects affected / exposed	Additional description: Foetal death	
	11 / 1236 (0.89%)	
	0 / 11	
occurrences causally related to treatment / all	0 / 4	
deaths causally related to treatment / all	0 / 4	
Foetal growth restriction subjects affected / exposed	Additional description: Foetal growth restriction	
	5 / 1236 (0.40%)	
	0 / 5	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Foetal hypokinesia subjects affected / exposed	Additional description: Foetal hypokinesia	
	1 / 1236 (0.08%)	
	0 / 1	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Gestational Diabetes subjects affected / exposed	Additional description: Gestational diabetes	
	2 / 1236 (0.16%)	
	0 / 2	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Haemorrhage in pregnancy subjects affected / exposed	Additional description: Haemorrhage in pregnancy	
	7 / 1236 (0.57%)	
	0 / 7	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
HELLP syndrome subjects affected / exposed	Additional description: HELLP syndrome	
	1 / 1236 (0.08%)	
	0 / 1	
occurrences causally related to treatment / all	0 / 0	
deaths causally related to treatment / all	0 / 0	
Hyperemesis gravidarum	Additional description: Hyperemesis gravidarum	

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, Polyhydraminos	Additional description: Shortened cervix, Polyhydraminos		
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			
Additional description: Abdominal pain, Pyrexia			
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		
Additional description: Blood pressure increased, Blood glucose			
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		
Additional description: Blood pressure increased, Headache			
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		
Additional description: Blood pressure increased, Pulmonary edema			
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		
Additional description: Cholecystitis, Cholelithiasis, Pancreatitis			
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		
Additional description: Cholestasis, HELLP			
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		
Additional description: Chorioamnionitis, Sepsis			
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 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Anaphylactic reaction		
	1 / 1236 (0.08%)		
	0 / 1		
Milk allergy subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Milk allergy		
	0 / 1236 (0.00%)		
	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		
	0 / 1236 (0.00%)		
	0 / 0		
Scrotal mass subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Scrotal mass		
	0 / 1236 (0.00%)		
	0 / 0		
Shortened cervix subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Shortened cervix		
	2 / 1236 (0.16%)		
	0 / 2		
Vaginal haemorrhage subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	Additional description: Vaginal haemorrhage		
	3 / 1236 (0.24%)		
	0 / 3		
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 / 1236 (0.00%)		
	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	Additional description: Mental disorder		
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	Additional description: Blood bilirubin increased		
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	Additional description: Acute fatty liver of pregnancy		
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	Additional description: Cow's milk intolerance, Gastroesophageal reflux disease		
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 subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	9 / 1364 (0.66%) 9	14 / 1374 (1.02%) 14
Foetal hypokinesia			

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

subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Contractions, Vaginal haemorrhage, Premature rupture of membranes	Additional description: Contractions, Vaginal haemorrhage, Premature rupture of membranes		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Low birth weight baby, Oligohydramnios	Additional description: Low birth weight baby, Oligohydramnios		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Placental transfusion syndrome, Oligohydramnios	Additional description: Placental transfusion syndrome, Oligohydramnios		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain lower, Contractions	Additional description: Abdominal pain lower, Contractions		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abortion threatened	Additional description: Abortion threatened		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Caesarean section	Additional description: Caesarean section		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Cephalhaematoma	Additional description: Cephalhaematoma		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	2 / 1374 (0.15%) 2
Cervical incompetence	Additional description: Cervical incompetence		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Prenatal screening test abnormal	Additional description: Prenatal screening test abnormal		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Low birth weight baby	Additional description: Low birth weight baby		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	2 / 1374 (0.15%) 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 occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Labour subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Large for dates baby subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Foetal distress syndrome subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Placental insufficiency subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
General disorders and administration site conditions			
Chest pain	Additional description: Chest pain		
subjects affected / exposed occurrences (all)	20 / 1227 (1.63%) 20	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Fatigue	Additional description: Fatigue		
subjects affected / exposed occurrences (all)	35 / 1227 (2.85%) 35	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Malaise	Additional description: Malaise		
subjects affected / exposed occurrences (all)	21 / 1227 (1.71%) 21	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Oedema	Additional description: Oedema		
subjects affected / exposed occurrences (all)	33 / 1227 (2.69%) 33	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Oedema peripheral	Additional description: Oedema peripheral		
subjects affected / exposed occurrences (all)	93 / 1227 (7.58%) 93	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Pyrexia	Additional description: Pyrexia		
subjects affected / exposed occurrences (all)	13 / 1227 (1.06%) 13	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal cramping, Vaginal discharge	Additional description: Abdominal cramping, Vaginal discharge		

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

subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain upper, Nausea	Additional description: Abdominal pain upper, Nausea		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain upper, Headache, Oedema peripheral	Additional description: Abdominal pain upper, Headache, Oedema peripheral		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain, Diarrhoea, Back pain, Vaginal discharge	Additional description: Abdominal pain, Diarrhoea, Back pain, Vaginal discharge		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain, Back pain, Visual impairment	Additional description: Abdominal pain, Back pain, Visual impairment		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain, Headache, Oedema peripheral	Additional description: Abdominal pain, Headache, Oedema peripheral		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain, Malaise, Heart rate increased, Dehydration	Additional description: Abdominal pain, Malaise, Heart rate increased, Dehydration		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain, Vaginal haemorrhage, Cholestasis of pregnancy	Additional description: Abdominal pain, Vaginal haemorrhage, Cholestasis of pregnancy		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain, Vomiting, Tachypnoea	Additional description: Abdominal pain, Vomiting, Tachypnoea		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Back pain, Constipation	Additional description: Back pain, Constipation		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Back pain, Contractions	Additional description: Back pain, Contractions		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 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 occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dyspnoea, Headache, Oedema, Protein urine, Blood urine	Additional description: Dyspnoea, Headache, Oedema, Protein urine, Blood urine		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dyspnoea, Chest pain	Additional description: Dyspnoea, Chest pain		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Fatigue, Abdominal pain, Nausea	Additional description: Fatigue, Abdominal pain, Nausea		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Fatigue, Oropharyngeal pain, Abdominal pain upper	Additional description: Fatigue, Oropharyngeal pain, Abdominal pain upper		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Amylase increased	Additional description: Headache, Amylase increased		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Arthralgia	Additional description: Headache, Arthralgia		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Back pain	Additional description: Headache, Back pain		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Diarrhoea	Additional description: Headache, Diarrhoea		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Oedema	Additional description: Headache, Oedema		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Oedema peripheral	Additional description: Headache, Oedema peripheral		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Pain in extremity	Additional description: Headache, Pain in extremity		

subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Protein urine	Additional description: Headache, Protein urine		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Proteinuria	Additional description: Headache, Proteinuria		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Urine protein/creatinine ratio	Additional description: Headache, Urine protein/creatinine ratio		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Dizziness, Night sweats	Additional description: Headache, Dizziness, Night sweats		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Ear pain, Nausea, Dyspepsia	Additional description: Headache, Ear pain, Nausea, Dyspepsia		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Pain in extremity, Diarrhoea	Additional description: Headache, Pain in extremity, Diarrhoea		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Nausea, Back pain	Additional description: Headache, Nausea, Back pain		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Oedema, Visual impairment	Additional description: Headache, Oedema, Visual impairment, Abdominal pain upper, Dyspepsia		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Oedema peripheral, Visual impairment, Abdominal pain upper, Dyspepsia	Additional description: Headache, Oedema peripheral, Visual impairment, Abdominal pain upper, Dyspepsia		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Headache, Oedema, Abdominal pain, Hypertension	Additional description: Headache, Oedema, Abdominal pain, Hypertension		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 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, Chorioamniotitis	Additional description: Premature rupture of membranes, Chorioamniotitis		
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
Additional description: Vaginal discomfort, Back pain, Dysuria			
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
Additional description: Vaginal haemorrhage, Pain			
Vaginal haemorrhage, Pain subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Additional description: Vaginal haemorrhage, Pelvic pain			
Vaginal haemorrhage, Pelvic pain subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Additional description: Vaginal haemorrhage, Vaginal discharge			
Vaginal haemorrhage, Vaginal discharge subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Additional description: Vaginal haemorrhage, Diarrhoea, Incontinence			
Vaginal haemorrhage, Diarrhoea, Incontinence subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Additional description: Visual impairment, Dyspnoea, Polyhydramnios			
Visual impairment, Dyspnoea, Polyhydramnios subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Additional description: Vomiting, Dizziness, Migraine			
Vomiting, Dizziness, Migraine subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Additional description: Abdominal pain, Back pain, Vaginal discharge			
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
Additional description: Asthenia			
Asthenia subjects affected / exposed occurrences (all)	7 / 1227 (0.57%) 7	0 / 1364 (0.00%) 0	7 / 1374 (0.51%) 7
Additional description: Chest discomfort			
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 occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Breast cyst	Additional description: Breast cyst		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Breast pain	Additional description: Breast pain		
subjects affected / exposed occurrences (all)	4 / 1227 (0.33%) 4	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Breast tenderness	Additional description: Breast tenderness		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Cervix disorder	Additional description: Cervix disorder		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vulvovaginal pain	Additional description: Vulvovaginal pain		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vulvovaginal burning sensation	Additional description: Vulvovaginal burning sensation		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Coital bleeding	Additional description: Coital bleeding		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Pelvic discomfort	Additional description: Pelvic discomfort		
subjects affected / exposed occurrences (all)	7 / 1227 (0.57%) 7	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Uterine cervical pain	Additional description: Uterine cervical pain		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vulvovaginal pruritus	Additional description: Vulvovaginal pruritus		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Cervical friability	Additional description: Cervical friability		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Cervix haematoma uterine	Additional description: 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	Additional description: 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	Additional description: 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	Additional description: 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	Additional description: Sinus congestion		
subjects affected / exposed	3 / 1227 (0.24%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	3	0	0
Rhinorrhoea	Additional description: Rhinorrhoea		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic	Additional description: 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 occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood gases abnormal	Additional description: Blood gases abnormal		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	3 / 1374 (0.22%) 3
Blood iron decreased	Additional description: Blood iron decreased		
subjects affected / exposed occurrences (all)	8 / 1227 (0.65%) 8	0 / 1364 (0.00%) 0	3 / 1374 (0.22%) 3
Blood lactate dehydrogenase	Additional description: Blood lactate dehydrogenase		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood potassium decreased	Additional description: Blood potassium decreased		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure abnormal	Additional description: Blood pressure abnormal		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood pressure decreased	Additional description: Blood pressure decreased		
subjects affected / exposed occurrences (all)	4 / 1227 (0.33%) 4	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood sodium	Additional description: Blood sodium		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood sodium abnormal	Additional description: Blood sodium abnormal		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood thyroid stimulating hormone	Additional description: Blood thyroid stimulating hormone		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood urea	Additional description: Blood urea		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Blood uric acid increased	Additional description: Blood uric acid increased		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 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	Additional description: 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	Additional description: 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	Additional description: 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 occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Serum ferritin decreased subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Platelet count decreased subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Platelet count subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	2 / 1364 (0.15%) 2	1 / 1374 (0.07%) 1
Physical examination subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Oxygen saturation decreased subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	1 / 1364 (0.07%) 1	1 / 1374 (0.07%) 1
Heart rate increased subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Heart rate abnormal subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Haemoglobin subjects affected / exposed occurrences (all)	12 / 1227 (0.98%) 12	0 / 1364 (0.00%) 0	2 / 1374 (0.15%) 2
Haemoglobin decreased subjects affected / exposed occurrences (all)	12 / 1227 (0.98%) 12	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Haematocrit subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	2 / 1374 (0.15%) 2
Glycosylated haemoglobin subjects affected / exposed occurrences (all)	6 / 1227 (0.49%) 6	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Glucose urine present			

subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Glucose urine subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Glucose tolerance test subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Injury, poisoning and procedural complications			
Fall	Additional description: Fall		
subjects affected / exposed occurrences (all)	9 / 1227 (0.73%) 9	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Accidental overdose	Additional description: Accidental overdose		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Accidental poisoning	Additional description: Accidental poisoning		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Animal bite	Additional description: Animal bite (dog)		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Ankle fracture	Additional description: Ankle fracture		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Clavicle fracture	Additional description: Clavicle fracture		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 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 occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Foreign body	Additional description: Foreign body		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 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 occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Foot fracture subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Femoral nerve injury subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Congenital, familial and genetic disorders			
Additional description: Congenital cardiovascular anomaly			
Congenital cardiovascular anomaly subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	1 / 1374 (0.07%) 1
Additional description: Apert's syndrome			
Apert's syndrome subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Additional description: Atrial septal defect			
Atrial septal defect subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	1 / 1364 (0.07%) 1	2 / 1374 (0.15%) 2
Additional description: Cataract congenital			
Cataract congenital subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Additional description: Congenital anomaly			
Congenital anomaly subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Additional description: Congenital central nervous system anomaly			
Congenital central nervous system anomaly subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Additional description: Cryptorchism			
Cryptorchism subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Additional description: Developmental hip dysplasia			
Developmental hip dysplasia subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	1 / 1374 (0.07%) 1
Additional description: Congenital skin dimples			
Congenital skin dimples			

subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	3 / 1374 (0.22%) 3
Skeletal dysplasia	Additional description: Skeletal dysplasia		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Congenital naevus	Additional description: Congenital naevus		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	1 / 1374 (0.07%) 1
Naevus flammeus	Additional description: Naevus flammeus		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Ectopic kidney			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Skull malformation	Additional description: Skull malformation		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Anomaly of external ear congenital			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Congenital Eustachian tube anomaly	Additional description: Congenital Eustachian tube anomaly		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Congenital oral malformation			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Laryngomalacia			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Trisomy 18			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Congenital eye naevus			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	2 / 1364 (0.15%) 2	0 / 1374 (0.00%) 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 occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Hydrocele subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	3 / 1364 (0.22%) 3	3 / 1374 (0.22%) 3
Heart disease congenital subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Haemangioma congenital subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	2 / 1374 (0.15%) 2
Gastroschisis subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Galactosaemia subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Exomphalos subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Congenital hypothyroidism subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Cardiac disorders			
Palpitations	Additional description: Palpitations		
subjects affected / exposed occurrences (all)	14 / 1227 (1.14%) 14	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Arrhythmia	Additional description: Arrhythmia		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	1 / 1364 (0.07%) 1	1 / 1374 (0.07%) 1
Bradycardia foetal	Additional description: Bradycardia foetal		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	3 / 1374 (0.22%) 3
Bradycardia	Additional description: Bradycardia		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0

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

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

subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Burning sensation	Additional description: Burning sensation		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Convulsion	Additional description: Convulsion		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Depressed level of consciousness	Additional description: Depressed level of consciousness		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Hyperglycaemic seizure	Additional description: Hyperglycaemic seizure		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Restless legs syndrome			
subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
VIIth nerve paralysis			
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
VIth nerve paralysis			
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Tremor			
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Tension headache			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Syncope			
subjects affected / exposed occurrences (all)	4 / 1227 (0.33%) 4	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Somnolence			
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 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	Additional description: Acoustic stimulation tests abnormal		
Acoustic stimulation tests abnormal subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Deafness	Additional description: Deafness		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Ear pain	Additional description: Ear pain		
subjects affected / exposed occurrences (all)	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	Additional description: Conjunctivitis		
Conjunctivitis subjects affected / exposed occurrences (all)	14 / 1227 (1.14%) 14	1 / 1364 (0.07%) 1	6 / 1374 (0.44%) 6
Vision Blurred	Additional description: Vision Blurred		
subjects affected / exposed occurrences (all)	20 / 1227 (1.63%) 20	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Visual impairment	Additional description: Visual impairment		
subjects affected / exposed occurrences (all)	53 / 1227 (4.32%) 53	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Diabetic retinopathy	Additional description: Diabetic retinopathy		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Dry eye	Additional description: Dry eye		
subjects affected / exposed occurrences (all)	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 occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Chorioretinopathy	Additional description: Chorioretinopathy		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vitreous floaters	Additional description: Vitreous floaters		
subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Visual field defect	Additional description: Visual field defect		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Scintillating scotoma	Additional description: Scintillating scotoma		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Photopsia	Additional description: Photopsia		
subjects affected / exposed occurrences (all)	10 / 1227 (0.81%) 10	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Photophobia	Additional description: Photophobia		
subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Periorbital oedema	Additional description: Periorbital oedema		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Eye pain	Additional description: Eye pain		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Gastrointestinal disorders	Additional description: Gastrointestinal disorders		
Abdominal pain lower	Additional description: Abdominal pain lower		
subjects affected / exposed occurrences (all)	8 / 1227 (0.65%) 8	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain	Additional description: Abdominal pain		
subjects affected / exposed occurrences (all)	57 / 1227 (4.65%) 57	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Abdominal pain upper	Additional description: Abdominal pain upper		
subjects affected / exposed occurrences (all)	82 / 1227 (6.68%) 82	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0

Diarrhoea	Additional description: Diarrhoea		
subjects affected / exposed	33 / 1227 (2.69%)	0 / 1364 (0.00%)	1 / 1374 (0.07%)
occurrences (all)	33	0	1
Constipation	Additional description: Constipation		
subjects affected / exposed	46 / 1227 (3.75%)	0 / 1364 (0.00%)	2 / 1374 (0.15%)
occurrences (all)	46	0	2
Dyspepsia	Additional description: Dyspepsia		
subjects affected / exposed	126 / 1227 (10.27%)	1 / 1364 (0.07%)	0 / 1374 (0.00%)
occurrences (all)	126	1	0
Gastroesophageal reflux disease	Additional description: Gastroesophageal reflux disease		
subjects affected / exposed	61 / 1227 (4.97%)	5 / 1364 (0.37%)	4 / 1374 (0.29%)
occurrences (all)	61	5	4
Nausea	Additional description: Nausea		
subjects affected / exposed	85 / 1227 (6.93%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	85	0	0
Toothache	Additional description: Toothache		
subjects affected / exposed	7 / 1227 (0.57%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	7	0	0
Vomiting	Additional description: Vomiting		
subjects affected / exposed	90 / 1227 (7.33%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	90	0	0
Abdominal pain, Nausea	Additional description: Abdominal pain, Nausea		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Constipation, Dyspepsia	Additional description: Constipation, Dyspepsia		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed	8 / 1227 (0.65%)	0 / 1364 (0.00%)	6 / 1374 (0.44%)
occurrences (all)	8	0	6
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
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	Additional description: Scar pain		
subjects affected / exposed	2 / 1227 (0.16%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	2	0	0
Swelling face	Additional description: Swelling face		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Skin irritation	Additional description: Skin irritation		
subjects affected / exposed	1 / 1227 (0.08%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	1	0	0
Rosacea	Additional description: Rosacea		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Rash pruritic	Additional description: Rash pruritic		
subjects affected / exposed	0 / 1227 (0.00%)	0 / 1364 (0.00%)	0 / 1374 (0.00%)
occurrences (all)	0	0	0
Petechiae	Additional description: 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 occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Haematuria subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Glycosuria subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Urinary hesitation subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Endocrine disorders			
Basedow's disease subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Hypothyroidism subjects affected / exposed occurrences (all)	9 / 1227 (0.73%) 9	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	19 / 1227 (1.55%) 19	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	68 / 1227 (5.54%) 68	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	36 / 1227 (2.93%) 36	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	20 / 1227 (1.63%) 20	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Musculoskeletal pain			

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

subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Plantar fasciitis subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Pain in jaw subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Joint stiffness subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Infections and infestations			
Candidiasis subjects affected / exposed occurrences (all)	9 / 1227 (0.73%) 9	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Fungal infection subjects affected / exposed occurrences (all)	16 / 1227 (1.30%) 16	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Gastroenteritis viral subjects affected / exposed occurrences (all)	34 / 1227 (2.77%) 34	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Influenza subjects affected / exposed occurrences (all)	16 / 1227 (1.30%) 16	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Lower respiratory tract infection subjects affected / exposed occurrences (all)	24 / 1227 (1.96%) 24	1 / 1364 (0.07%) 1	0 / 1374 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	80 / 1227 (6.52%) 80	2 / 1364 (0.15%) 2	1 / 1374 (0.07%) 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 occurrences (all)	10 / 1227 (0.81%) 10	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Ureaplasma test positive	Additional description: Ureaplasma test positive		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Chikungunya virus infection	Additional description: Chikungunya virus infectiom		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Oral herpes	Additional description: Oral herpes		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Vulvovaginal mycotic infection	Additional description: Vulvovaginal mycotic infection		
subjects affected / exposed occurrences (all)	5 / 1227 (0.41%) 5	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Uterine infection	Additional description: Uterine infection		
subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Bacterial vaginosis	Additional description: Bacterial vaginosis		
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Nail infection			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Lung infection			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Escherichia infection			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	1 / 1374 (0.07%) 1
Staphylococcal infection			
subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Parvovirus infection			
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 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 occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Herpes virus infection subjects affected / exposed occurrences (all)	3 / 1227 (0.24%) 3	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Herpes simplex subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Hand-foot-and-mouth disease subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Furuncle subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Eye infection subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Impetigo subjects affected / exposed occurrences (all)	1 / 1227 (0.08%) 1	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Laryngitis subjects affected / exposed occurrences (all)	2 / 1227 (0.16%) 2	0 / 1364 (0.00%) 0	0 / 1374 (0.00%) 0
Metabolism and nutrition disorders			
Hypoglycaemia	Additional description: Hypoglycaemia		
subjects affected / exposed occurrences (all)	5 / 1227 (0.41%) 5	9 / 1364 (0.66%) 9	14 / 1374 (1.02%) 14
Cow's milk intolerance	Additional description: Cow's milk intolerance		
subjects affected / exposed occurrences (all)	0 / 1227 (0.00%) 0	1 / 1364 (0.07%) 1	1 / 1374 (0.07%) 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 occurrences (all)	0 / 1236 (0.00%) 0		
Melanocytic naevus			
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Vascular disorders			
Gestational hypertension	Additional description: Gestational hypertension		
subjects affected / exposed occurrences (all)	12 / 1236 (0.97%) 12		
Hypertension	Additional description: Hypertension		
subjects affected / exposed occurrences (all)	42 / 1236 (3.40%) 42		
Subgaleal haematoma	Additional description: Subgaleal haematoma		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 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 occurrences (all)	0 / 1236 (0.00%) 0		
Bartholin's cyst removal	Additional description: Bartholin's cyst removal		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
External cephalic version	Additional description: Failed external cephalic version		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Respiratory support	Additional description: Respiratory support		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Transfusion	Additional description: Transfusion		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Wound treatment			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Tooth extraction			
subjects affected / exposed occurrences (all)	3 / 1236 (0.24%) 3		
Office visit			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Ureteral stent insertion			
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Surgery			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Tooth repair			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Physiotherapy			
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
General anaesthesia			

subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Forceps delivery subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Episiotomy subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Pregnancy, puerperium and perinatal conditions			
Foetal growth restriction			
Additional description: Foetal growth restriction			
subjects affected / exposed occurrences (all)	5 / 1236 (0.40%) 5		
Foetal hypokinesia			
Additional description: Foetal hypokinesia			
subjects affected / exposed occurrences (all)	92 / 1236 (7.44%) 92		
Gestational diabetes			
Additional description: Gestational diabetes			
subjects affected / exposed occurrences (all)	90 / 1236 (7.28%) 90		
Jaundice neonatal			
Additional description: Jaundice neonatal			
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Polyhydramnios			
Additional description: Polyhydramnios			
subjects affected / exposed occurrences (all)	13 / 1236 (1.05%) 13		
Postpartum haemorrhage			
Additional description: Postpartum haemorrhage			
subjects affected / exposed occurrences (all)	32 / 1236 (2.59%) 32		
Pre-eclampsia			
Additional description: Pre-eclampsia			
subjects affected / exposed occurrences (all)	18 / 1236 (1.46%) 18		
Premature baby			
Additional description: Premature baby			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 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 occurrences (all)	0 / 1236 (0.00%) 0		
Cervical incompetence	Additional description: Cervical incompetence		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Prenatal screening test abnormal	Additional description: Prenatal screening test abnormal		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Low birth weight baby	Additional description: Low birth weight baby		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Amniorrhoea	Additional description: Amniorrhoea		
subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Placenta accreta	Additional description: Placenta accreta		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Labour pain	Additional description: Labour pain		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Meconium stain	Additional description: Meconium stain		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Foetal macrosomia	Additional description: Foetal macrosomia		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Labour induction	Additional description: Labour induction		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Imminent abortion	Additional description: Imminent abortion		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Meconium abnormal	Additional description: Meconium abnormal		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Vomiting in pregnancy	Additional description: Vomiting in pregnancy		

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

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

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

haemorrhage, Cholestasis of pregnancy subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Abdominal pain, Vomiting, Tachypnoea			
Abdominal pain, Vomiting, Tachypnoea subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Back pain, Constipation			
Back pain, Constipation subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Back pain, Contractions			
Back pain, Contractions subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Back pain, Pollakiuria			
Back pain, Pollakiuria subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Back pain, Right sided pain, Vomiting			
Back pain, Right sided pain, Vomiting subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Back pain, Oropharyngeal pain, Diarrhoea, Pollakiuria			
Back pain, Oropharyngeal pain, Diarrhoea, Pollakiuria subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Blood glucose and Urine ketone body present			
Blood glucose, Urine ketone body present subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Blood glucose increased, Nausea			
Blood glucose increased, Nausea subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Blood pressure increased, Dyspnoea			
Blood pressure increased, Dyspnoea subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Blood pressure increased, Anogenital warts			
Blood pressure increased, Anogenital warts subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Blood pressure increased, Headache			
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		
Chorioamniotitis, Creatine urine increased	Additional description: Chorioamniotitis, 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 occurrences (all)	1 / 1236 (0.08%) 1		
Diarrhoea, Nausea, Sensation of pressure, Vaginal discharge	Additional description: Diarrhoea, Nausea, Sensation of pressure, Vaginal discharge		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Dry eye, Dry mouth	Additional description: Dry eye, Dry mouth		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Dyspnoea, Asthenia, Vision blurred	Additional description: Dyspnoea, Asthenia, Vision blurred		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Dyspnoea, Diarrhoea, Myalgia, Abdominal pain, Back pain	Additional description: Dyspnoea, Diarrhoea, Myalgia, Abdominal pain, Back pain		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Dyspnoea, Headache, Oedema, Protein urine, Blood urine	Additional description: Dyspnoea, Headache, Oedema, Protein urine, Blood urine		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Dyspnoea, Chest pain	Additional description: Dyspnoea, Chest pain		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Fatigue, Abdominal pain, Nausea	Additional description: Fatigue, Abdominal pain, Nausea		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Fatigue, Oropharyngeal pain, Abdominal pain upper	Additional description: Fatigue, Oropharyngeal pain, Abdominal pain upper		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Headache, Amylase increased	Additional description: Headache, Amylase increased		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Headache, Arthralgia	Additional description: Headache, Arthralgia		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Headache, Back pain	Additional description: Headache, Back pain		

subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Headache, Diarrhoea	Additional description: Headache, Diarrhoea		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Headache, Oedema	Additional description: Headache, Oedema		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Headache, Oedema peripheral	Additional description: Headache, Oedema peripheral		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Headache, Pain in extremity	Additional description: Headache, Pain in extremity		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Headache, Protein urine	Additional description: Headache, Protein urine		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Headache, Proteinuria	Additional description: Headache, Proteinuria		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Headache, Urine protein/creatinine ratio	Additional description: Headache, Urine protein/creatinine ratio		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Headache, Dizziness, Night sweats	Additional description: Headache, Dizziness, Night sweats		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Headache, Ear pain, Nausea, Dyspepsia	Additional description: Headache, Ear pain, Nausea, Dyspepsia		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Headache, Pain in extremity, Diarrhoea	Additional description: Headache, Pain in extremity, Diarrhoea		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 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, Chorioamniotitis subjects affected / exposed occurrences (all)	Additional description: Premature rupture of membranes, Chorioamniotitis 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 occurrences (all)	1 / 1236 (0.08%) 1		
Sciatica, Skin infection	Additional description: Sciatica, Skin infection		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Shoulder dystocia, Erb's palsy	Additional description: Shoulder dystocia, Erb's palsy		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Musculoskeletal pain, Rash	Additional description: Shoulder pain, Rash		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Thirst, Hyperhidrosis	Additional description: Thirst, Hyperhidrosis		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Vaginal discomfort, Back pain, Dysuria	Additional description: Vaginal discomfort, Back pain, Dysuria		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Vaginal haemorrhage, Pain	Additional description: Vaginal haemorrhage, Pain		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Vaginal haemorrhage, Pelvic pain	Additional description: Vaginal haemorrhage, Pelvic pain		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Vaginal haemorrhage, Vaginal discharge	Additional description: Vaginal haemorrhage, Vaginal discharge		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Vaginal haemorrhage, Diarrhoea, Incontinence	Additional description: Vaginal haemorrhage, Diarrhoea, Incontinence		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Visual impairment, Dyspnoea, Polyhydramnios	Additional description: Visual impairment, Dyspnoea, Polyhydramnios		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 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 occurrences (all)	0 / 1236 (0.00%) 0		
Reproductive system and breast disorders			
Additional description: Pelvic pain			
Pelvic pain subjects affected / exposed occurrences (all)	31 / 1236 (2.51%) 31		
Additional description: Vaginal discharge			
Vaginal discharge subjects affected / exposed occurrences (all)	18 / 1236 (1.46%) 18		
Additional description: Vaginal haemorrhage			
Vaginal haemorrhage subjects affected / exposed occurrences (all)	61 / 1236 (4.94%) 61		
Additional description: Bartholinitis			
Bartholinitis subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Breast cyst			
Breast cyst subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Breast pain			
Breast pain subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Breast tenderness			
Breast tenderness subjects affected / exposed occurrences (all)	3 / 1236 (0.24%) 3		
Additional description: Cervix disorder			
Cervix disorder subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Vulvovaginal pain			
Vulvovaginal pain subjects affected / exposed occurrences (all)	3 / 1236 (0.24%) 3		
Additional description: Vulvovaginal burning sensation			
Vulvovaginal burning sensation subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Coital bleeding			
Coital bleeding			

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

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

subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Sleep apnoea syndrome subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Sinus congestion subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Rhinitis allergic subjects affected / exposed occurrences (all)	3 / 1236 (0.24%) 3		
Productive cough subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Pleural effusion subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Nasal congestion subjects affected / exposed occurrences (all)	12 / 1236 (0.97%) 12		
Pulmonary haemorrhage neonatal subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Psychiatric disorders			
Insomnia	Additional description: Insomnia		
subjects affected / exposed occurrences (all)	17 / 1236 (1.38%) 17		
Anxiety	Additional description: Anxiety		
subjects affected / exposed occurrences (all)	5 / 1236 (0.40%) 5		
Anxiety attack	Additional description: Anxiety attack		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 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 occurrences (all)	0 / 1236 (0.00%) 0		
Hepatic pain subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Investigations			
Blood pressure increased subjects affected / exposed occurrences (all)	40 / 1236 (3.24%) 40	Additional description: Blood pressure increased	
Protein urine present subjects affected / exposed occurrences (all)	13 / 1236 (1.05%) 13	Additional description: Protein urine present	
Serum ferritin subjects affected / exposed occurrences (all)	7 / 1236 (0.57%) 7	Additional description: Serum ferritin	
Blood pressure increased, Protein in urine subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1	Additional description: Blood pressure increased, Protein in urine	
Blood pressure increased, Proteinuria subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2	Additional description: Blood pressure increased, Proteinuria	
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0	Additional description: Alanine aminotransferase increased	
Albumin urine subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0	Additional description: Albumin urine test	
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	3 / 1236 (0.24%) 3	Additional description: Aspartate aminotransferase increased	
Blood bicarbonate subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0	Additional description: Blood bicarbonate	
Blood bilirubin		Additional description: Blood bilirubin	

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

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

subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Amniotic fluid volume decreased	Additional description: Amniotic fluid volume decreased		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Urine cannabinoids increased subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Urine analysis abnormal subjects affected / exposed occurrences (all)	9 / 1236 (0.73%) 9		
Hepatic enzyme increased subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Gastric pH decreased subjects affected / exposed occurrences (all)	9 / 1236 (0.73%) 9		
Total bile acids subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Base excess subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Urine ketone body present subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Urine protein/creatinine ratio increased subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Urine albumin/creatinine ratio increased subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 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 occurrences (all)	11 / 1236 (0.89%) 11		
Haemoglobin decreased subjects affected / exposed occurrences (all)	5 / 1236 (0.40%) 5		
Haematocrit subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Glycosylated haemoglobin subjects affected / exposed occurrences (all)	7 / 1236 (0.57%) 7		
Glucose urine present subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Glucose urine subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Glucose tolerance test subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Injury, poisoning and procedural complications			
Fall	Additional description: Fall		
subjects affected / exposed occurrences (all)	13 / 1236 (1.05%) 13		
Accidental overdose	Additional description: Accidental overdose		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Accidental poisoning	Additional description: Accidental poisoning		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Animal bite	Additional description: Animal bite (dog)		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Ankle fracture	Additional description: Ankle fracture		

subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Clavicle fracture	Additional description: Clavicle fracture		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 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 occurrences (all)	0 / 1236 (0.00%) 0		
Foreign body	Additional description: Foreign body		
subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Skeletal injury			
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Limb injury			
subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Procedural complication			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Thermal burn			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Contusion			
subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Muscle strain			
subjects affected / exposed occurrences (all)	4 / 1236 (0.32%) 4		
Excoriation			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Uterine rupture			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 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			
Additional description: Congenital central nervous system anomaly			
subjects affected / exposed	1 / 1236 (0.08%)		
occurrences (all)	1		
Cryptorchism			
Additional description: Cryptorchism			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Developmental hip dysplasia			
Additional description: Developmental hip dysplasia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital skin dimples			
Additional description: Congenital skin dimples			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Skeletal dysplasia			
Additional description: Skeletal dysplasia			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Congenital naevus			
Additional description: Congenital naevus			
subjects affected / exposed	0 / 1236 (0.00%)		
occurrences (all)	0		
Naevus flammeus			
Additional description: 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			
Additional description: 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			
Additional description: 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 occurrences (all)	0 / 1236 (0.00%) 0		
Patent ductus arteriosus subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Limb malformation subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Kidney duplex subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Hypospadias subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Hydrocele subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Heart disease congenital subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Haemangioma congenital subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Gastroschisis subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Galactosaemia subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Exomphalos subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Congenital hypothyroidism subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 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 occurrences (all)	13 / 1236 (1.05%) 13		
Migraine	Additional description: Migraine		
subjects affected / exposed occurrences (all)	22 / 1236 (1.78%) 22		
Sciatica	Additional description: Sciatica		
subjects affected / exposed occurrences (all)	18 / 1236 (1.46%) 18		
Aphasia	Additional description: Aphasia		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Apraxia	Additional description: Apraxia		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Burning sensation	Additional description: Burning sensation		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Convulsion	Additional description: Convulsion		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Depressed level of consciousness	Additional description: Depressed level of consciousness		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Hyperglycaemic seizure	Additional description: Hyperglycaemic seizure		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Restless legs syndrome			
subjects affected / exposed occurrences (all)	6 / 1236 (0.49%) 6		
VIIth nerve paralysis			
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
VIth nerve paralysis			
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Tremor			

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

Anaemia	Additional description: Anaemia	
subjects affected / exposed	54 / 1236 (4.37%)	
occurrences (all)	54	
Splenic cyst		
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Thrombocytopenia neonatal		
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Thrombocytopenia		
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Lymphadenopathy		
subjects affected / exposed	3 / 1236 (0.24%)	
occurrences (all)	3	
Ear and labyrinth disorders		
Acoustic stimulation tests abnormal	Additional description: Acoustic stimulation tests abnormal	
subjects affected / exposed	0 / 1236 (0.00%)	
occurrences (all)	0	
Deafness	Additional description: Deafness	
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	
Ear pain	Additional description: Ear pain	
subjects affected / exposed	7 / 1236 (0.57%)	
occurrences (all)	7	
Ear discomfort		
subjects affected / exposed	1 / 1236 (0.08%)	
occurrences (all)	1	
Tinnitus		
subjects affected / exposed	2 / 1236 (0.16%)	
occurrences (all)	2	
Eye disorders		
Conjunctivitis	Additional description: Conjunctivitis	
subjects affected / exposed	13 / 1236 (1.05%)	
occurrences (all)	13	
Vision Blurred	Additional description: Vision Blurred	

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

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

subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Constipation, Dyspepsia	Additional description: Constipation, Dyspepsia		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Abdominal discomfort	Additional description: Abdominal discomfort		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Dry mouth	Additional description: Dry mouth		
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Gastrointestinal inflammation	Additional description: Gastrointestinal inflammation		
subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Tooth abscess			
subjects affected / exposed occurrences (all)	4 / 1236 (0.32%) 4		
Retching			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Rectal haemorrhage			
subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Proctitis			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Periodontal disease			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Oesophageal spasm			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Mouth ulceration			
subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 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 occurrences (all)	2 / 1236 (0.16%) 2		
Flank pain subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Oral pain subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Skin and subcutaneous tissue disorders			
Additional description: Pruritus			
Pruritus subjects affected / exposed occurrences (all)	41 / 1236 (3.32%) 41		
Additional description: Rash			
Rash subjects affected / exposed occurrences (all)	11 / 1236 (0.89%) 11		
Additional description: Acne			
Acne subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Cafe au lait spots			
Cafe au lait spots subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Dermatitis atopic			
Dermatitis atopic subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Additional description: Dermatitis diaper			
Dermatitis diaper subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Additional description: Polymorphic eruption of pregnancy			
Polymorphic eruption of pregnancy subjects affected / exposed occurrences (all)	5 / 1236 (0.40%) 5		
Scar pain subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Swelling face subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 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 occurrences (all)	0 / 1236 (0.00%) 0		
Nephrotic syndrome subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Nephropathy subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Micturition urgency subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Ketonuria subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Haematuria subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Glycosuria subjects affected / exposed occurrences (all)	2 / 1236 (0.16%) 2		
Urinary hesitation subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Endocrine disorders			
Basedow's disease subjects affected / exposed occurrences (all)	0 / 1236 (0.00%) 0		
Hypothyroidism subjects affected / exposed occurrences (all)	3 / 1236 (0.24%) 3		
Hyperthyroidism subjects affected / exposed occurrences (all)	1 / 1236 (0.08%) 1		
Musculoskeletal and connective tissue disorders			

Additional description: Basedow's disease

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		
Polyarthritits 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 occurrences (all)	17 / 1236 (1.38%) 17		
Fungal infection	Additional description: Fungal infection		

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

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