



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) |
|-----------------------|--------------------|

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: -

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|---|---------------|
| 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

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| Arm title | Experimental Group |
|------------------|--------------------|

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 |

| <div>Variability estimate</div> | <div>Standard deviation</div> |
|---------------------------------|-------------------------------|
|---------------------------------|-------------------------------|

Adverse events

Adverse events information

Timeframe for reporting adverse events:

First administration of study treatment to last completed study visit

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|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

Dictionary used

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|-----------------|--------|
| Dictionary name | MedDRA |
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|--------------------|----|
| Dictionary version | 15 |
|--------------------|----|

Reporting groups

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|-----------------------|---------------|
| Reporting group title | active_mother |
|-----------------------|---------------|

Reporting group description: -

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|-----------------------|---------------|
| Reporting group title | active_infant |
|-----------------------|---------------|

Reporting group description:

Infants born to mothers in the active treatment group

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|-----------------------|----------------|
| Reporting group title | placebo_infant |
|-----------------------|----------------|

Reporting group description:

Infants born to mothers in the placebo group

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|-----------------------|----------------|
| Reporting group title | placebo_mother |
|-----------------------|----------------|

Reporting group description: -

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

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

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

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

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

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

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

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

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

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

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

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

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|---|--|------------------|------------------|
| 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 |

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

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

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

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

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

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|---|---|------------------|------------------|
| 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 | | |

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|---|--|------------------|------------------|
| 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 | | |

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

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

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

| | | | | |
|-----------------------------|---|------------------|------------------|------------------|
| Myalgia | Additional description: Myalgia | | | |
| | subjects affected / exposed | 0 / 1227 (0.00%) | 0 / 1364 (0.00%) | 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 | | | |
| | 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 | | |

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|---|---|------------------|------------------|
| 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 | | |

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|---|---|------------------|------------------|
| 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 | | |

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|---|--|------------------|------------------|
| 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 | | |

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|---|--|------------------|------------------|
| 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 |

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|---|---|--|--|
| 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 | | |

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|---|---|--|--|
| 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 | | |

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|---|--|--|--|
| 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 | | |

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| Failed induction of labour | Additional description: Failed induction of labour | | |
| subjects affected / exposed | 1 / 1236 (0.08%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| False labour | Additional description: False labour | | |
| subjects affected / exposed | 0 / 1236 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Foetal death | Additional description: Foetal death | | |
| subjects affected / exposed | 11 / 1236 (0.89%) | | |
| occurrences causally related to treatment / all | 0 / 11 | | |
| deaths causally related to treatment / all | 0 / 4 | | |
| Foetal growth restriction | Additional description: Foetal growth restriction | | |
| subjects affected / exposed | 5 / 1236 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Foetal hypokinesia | Additional description: Foetal hypokinesia | | |
| subjects affected / exposed | 1 / 1236 (0.08%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gestational Diabetes | Additional description: Gestational diabetes | | |
| subjects affected / exposed | 2 / 1236 (0.16%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Haemorrhage in pregnancy | Additional description: Haemorrhage in pregnancy | | |
| subjects affected / exposed | 7 / 1236 (0.57%) | | |
| occurrences causally related to treatment / all | 0 / 7 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| HELLP syndrome | Additional description: HELLP syndrome | | |
| subjects affected / exposed | 1 / 1236 (0.08%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hyperemesis gravidarum | Additional description: Hyperemesis gravidarum | | |

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|---|--|--|--|
| 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 | | |

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

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|---|---|--|--|
| 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 | | |

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

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|--|--|------------------|--|
| 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 | |

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|---|---|--|--|
| 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 | | |

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|---|--|--|--|
| 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 | | | |

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

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

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|---|---|--|--|
| 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 | | |

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|---|--|--|--|
| 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 | | | |

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|-----------------------------------|---|------------------|--|
| 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 | | |

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|---|--|--|--|
| 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 | | |

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|---|--|--|--|
| 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 | | |

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|---|---|--|--|
| 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 | | | |

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|---|--|--|
| 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 | |

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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| 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 | | | |

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

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| 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 | | |

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

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| 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 |

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| 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 | | |

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

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

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| 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 |

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| 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 |

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

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

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| 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 | | | |

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

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

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| 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 | | |

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

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| 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 | | | |

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| 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 | | |

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| 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 | | |

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

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

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| 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 | | | |

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

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

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| 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 | | | |

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

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

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| 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 | | | |

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

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| 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 |
| Bradycardia neonatal subjects affected / exposed occurrences (all) | 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 |
| Wolff-Parkinson-White syndrome subjects affected / exposed occurrences (all) | 1 / 1227 (0.08%) 1 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Ventricular extrasystoles subjects affected / exposed occurrences (all) | 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 |
| Tachycardia foetal subjects affected / exposed occurrences (all) | 0 / 1227 (0.00%) 0 | 0 / 1364 (0.00%) 0 | 1 / 1374 (0.07%) 1 |
| Sinus tachycardia subjects affected / exposed occurrences (all) | 2 / 1227 (0.16%) 2 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Pericarditis | | | |

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

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

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| 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 |

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

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| 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 | | | |
| subjects affected / exposed occurrences (all) | 3 / 1227 (0.24%) 3 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| 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 | | | |
| subjects affected / exposed occurrences (all) | 0 / 1227 (0.00%) 0 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Photopsia | | | |
| subjects affected / exposed occurrences (all) | 10 / 1227 (0.81%) 10 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Photophobia | | | |
| subjects affected / exposed occurrences (all) | 3 / 1227 (0.24%) 3 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Periorbital oedema | | | |
| subjects affected / exposed occurrences (all) | 0 / 1227 (0.00%) 0 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Eye pain | | | |
| subjects affected / exposed occurrences (all) | 1 / 1227 (0.08%) 1 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| 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 |

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

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| 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 |

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

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| 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 | | | |

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| 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 | | | |

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

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

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| 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 | Additional description: Candidiasis | | |
| subjects affected / exposed occurrences (all) | 9 / 1227 (0.73%) 9 | 1 / 1364 (0.07%) 1 | 0 / 1374 (0.00%) 0 |
| Fungal infection | Additional description: Fungal infection | | |
| subjects affected / exposed occurrences (all) | 16 / 1227 (1.30%) 16 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Gastroenteritis viral | Additional description: Gastroenteritis viral | | |
| subjects affected / exposed occurrences (all) | 34 / 1227 (2.77%) 34 | 0 / 1364 (0.00%) 0 | 0 / 1374 (0.00%) 0 |
| Influenza | Additional description: 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 | Additional description: 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 | Additional description: Nasopharyngitis | | |
| subjects affected / exposed occurrences (all) | 80 / 1227 (6.52%) 80 | 2 / 1364 (0.15%) 2 | 1 / 1374 (0.07%) 1 |

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

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| 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 | | | |

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| 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 | | | |

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

| | | | |
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| 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 |

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|---|-----------------------|-----------------------|-----------------------|
| 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 |

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

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|---------------------------------|--|--|--|
| 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 | | |

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

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

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|---|---|--|--|
| 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 | | |

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

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

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

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

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

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

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

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

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|---|---|--|--|
| 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 | | |

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| 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 | |

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

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

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|--|--|--|--|
| 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 | | |

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|-----------------------------|---|--|--|
| 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 | | | |

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

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

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

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

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| 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 | | |

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

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

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

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

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

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

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

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

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

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

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

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|--|--|--|--|
| 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 | | |

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

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

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

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

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

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

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

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

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

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|-----------------------------|--------------------------------------|--|--|
| 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 | | | |

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

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

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

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

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

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|-------------------------------------|------------------|--|--|
| 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>