



Clinical trial results:

TRAnexamic Acid for Preventing postpartum hemorrhage following a Cesarean Delivery : a multicenter randomised, double blind placebo controlled trial (TRAAP2)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2017-001144-36 |
| Trial protocol | FR |
| Global end of trial date | 08 April 2020 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 15 January 2022 |
| First version publication date | 15 January 2022 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | CHUBX2015/41 |
|-----------------------|--------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | CHU de Bordeaux |
| Sponsor organisation address | 12 rue Dubernat , Talence cedex, France, 33404 |
| Public contact | Pr Loïc Sentilhes, Pôle obstétrique, reproduction et gynécologie, Service de Gynécologie, +33 556 79 55 79, lois.sentilhes@chu-bordeaux.fr |
| Scientific contact | Pr Loïc Sentilhes, Pôle obstétrique, reproduction et gynécologie, Service de Gynécologie, +33 556 79 55 79, lois.sentilhes@chu-bordeaux.fr |

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 | 08 April 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 12 June 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 08 April 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To test the efficacy of a low dose of tranéxamic acid (1g) delivered within two minutes of the birth of a child by caesarean section versus placebo for the prevention of postpartum hemorrhage (PPH), defined by a Calculated blood loss of more than 1000mL (calculated blood loss = estimated blood volume x (preoperative Ht - preoperative Ht) / Ht preoperative (with estimated blood volume (in mL) = weight (in kg) x 85) A transfusion into globular concentrates before the second postpartum day (D2)

Protection of trial subjects:

The benefit/risk ratio was investigated in the study. TXA is a promising candidate as a preventive and morbidity-reducing treatment for PPH. In addition, it can be easily added to the delivery management protocol in all maternity hospitals worldwide.

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 12 June 2017 |
| 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 | France: 4551 |
| Worldwide total number of subjects | 4551 |
| EEA total number of subjects | 4551 |

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) | 4551 |
| From 65 to 84 years | 0 |

| | |
|-------------------|---|
| 85 years and over | 0 |
|-------------------|---|

Subject disposition

Recruitment

Recruitment details:

The total duration of the trial is 27 months, 24 months of inclusion and 3 months of post-partum follow-up (looking for thromboembolic complications or other remote side effects of the treatment).

The total duration of the research project is 38 months

30 centres in France participated in the study.

Pre-assignment

Screening details:

Inclusion criteria:

- Patient \geq 18 years
- Delivery by caesarean section
- Gestational age \geq 34 weeks + 0 days
- Blood cell count within 3 days prior to caesarean delivery
- Haemoglobin level at last blood sample $>$ 9g/dl
- Signed informed consent

Period 1

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

Arms

| | |
|------------------------------|-----------|
| Are arms mutually exclusive? | Yes |
| Arm title | TXA Group |

Arm description:

Experimental drug 1 is tranexamic acid injection (EXACYL® 1g-10mL I.V., injectable solution)

| | |
|--|------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | exacyl 1g-10mL |
| Investigational medicinal product code | SUB11214MIG |
| Other name | TRANEXAMIC ACID |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Il se présente sous forme de solution injectable conditionnée, pour une mise en aveugle, en flacon en verre de type 1 de 10 mL, à la concentration de 100mg /mL

La voie d'administration est la Voie intraveineuse lente stricte, durant la troisième phase du travail, dans les 3 minutes suivant la naissance d'un enfant par césarienne

| | |
|------------------|---------------|
| Arm title | Placebo Group |
|------------------|---------------|

Arm description:

Experimental drug 2 (placebo) is a 0.9%-10mL sodium chloride injection

| | |
|--|------------------------|
| Arm type | Placebo |
| Investigational medicinal product name | NaCl |
| Investigational medicinal product code | |
| Other name | Chlorure de sodium |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intravenous use |

Dosage and administration details:

Il se présente sous forme de solution injectable conditionnée, pour une mise en aveugle, en flacon en verre de type 1 de 10mL.

La voie d'administration est la Voie intraveineuse lente stricte

| Number of subjects in period 1 | TXA Group | Placebo Group |
|---------------------------------------|-----------|---------------|
| Started | 2276 | 2275 |
| Completed | 2222 | 2209 |
| Not completed | 54 | 66 |
| Consent withdrawn by subject | 6 | 8 |
| exclusion criteria | 44 | 54 |
| vaginal delivery | 4 | 4 |

Baseline characteristics

Reporting groups

| | |
|--|---------------|
| Reporting group title | TXA Group |
| Reporting group description: | |
| Experimental drug 1 is tranexamic acid injection (EXACYL® 1g-10mL I.V., injectable solution) | |
| Reporting group title | Placebo Group |
| Reporting group description: | |
| Experimental drug 2 (placebo) is a 0.9%-10mL sodium chloride injection | |

| Reporting group values | TXA Group | Placebo Group | Total |
|--|-----------|---------------|-------|
| Number of subjects | 2276 | 2275 | 4551 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 2276 | 2275 | 4551 |
| From 65-84 years | 0 | 0 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 2276 | 2275 | 4551 |
| Male | 0 | 0 | 0 |

Subject analysis sets

| | |
|---|-----------------------------|
| Subject analysis set title | Modified ITT TXA |
| Subject analysis set type | Modified intention-to-treat |
| Subject analysis set description: | |
| Population in underwent cesarean delivery analysed modified intention to treat in the group TXA | |
| Subject analysis set title | Modified ITT Placebo |
| Subject analysis set type | Modified intention-to-treat |
| Subject analysis set description: | |
| Population in underwent cesarean delivery analysed modified intention to treat in the placebo group | |

| Reporting group values | Modified ITT TXA | Modified ITT Placebo | |
|--|------------------|----------------------|--|
| Number of subjects | 2222 | 2209 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |

| | | | |
|--|------|------|--|
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 2222 | 2209 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 2222 | 2209 | |
| Male | 0 | 0 | |

End points

End points reporting groups

| | |
|---|-----------------------------|
| Reporting group title | TXA Group |
| Reporting group description: | |
| Experimental drug 1 is tranexamic acid injection (EXACYL® 1g-10mL I.V., injectable solution) | |
| Reporting group title | Placebo Group |
| Reporting group description: | |
| Experimental drug 2 (placebo) is a 0.9%-10mL sodium chloride injection | |
| Subject analysis set title | Modified ITT TXA |
| Subject analysis set type | Modified intention-to-treat |
| Subject analysis set description: | |
| Population in underwent cesarean delivery analysed modified intention to treat in the group TXA | |
| Subject analysis set title | Modified ITT Placebo |
| Subject analysis set type | Modified intention-to-treat |
| Subject analysis set description: | |
| Population in underwent cesarean delivery analysed modified intention to treat in the placebo group | |

Primary: Occurrence of postpartum haemorrhage before day 2

| | |
|--|---|
| End point title | Occurrence of postpartum haemorrhage before day 2 |
| End point description: | |
| incidence of Post Partum Haemorrhage defined as calculated blood loss >1000mL [calculated blood loss = estimated blood volume x (preoperative Ht - postoperative Ht)/preoperative Ht; where estimated blood volume (mL) = weight (kg) x 85], or the need for transfusion of at least 1 packed red blood cell before D2 | |
| End point type | Primary |
| End point timeframe: | |
| On the day of the cesarean delivery | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2086 | 2067 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 26.7 | 31.6 | | |
| No | 73.3 | 68.4 | | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Effect of study treatment on primary endpoints |
| Statistical analysis description: | |
| The incidence of PPH before D2 was compared between the two treatment groups using a mixed-effects Poisson regression model, with adjustment for the randomisation stratification factors of investigating centre and time of caesarean section (before or during labour). | |

| | |
|---|---|
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |
| Number of subjects included in analysis | 4153 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0032 |
| Method | Multiple imputation |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | 0.84 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.75 |
| upper limit | 0.94 |

Secondary: Calculated blood loss > 500 millilitres

| | |
|--|---|
| End point title | Calculated blood loss > 500 millilitres |
| End point description: | |
| Incidence of calculated blood loss > 500 mL | |
| End point type | Secondary |
| End point timeframe: | |
| Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss. | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2084 | 2066 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 58.2 | 64.2 | | |
| No | 41.8 | 35.8 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Calculated blood loss > 1000 millilitres

| | |
|--|--|
| End point title | Calculated blood loss > 1000 millilitres |
| End point description: | |
| Incidence of calculated blood loss > 1000 mL | |
| End point type | Secondary |
| End point timeframe: | |
| Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2084 | 2066 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 26.4 | 31.5 | | |
| No | 73.6 | 68.5 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Calculated blood loss > 1500 millilitres

| | |
|--|--|
| End point title | Calculated blood loss > 1500 millilitres |
| End point description: | |
| Incidence of severe PPH, defined as calculated blood loss greater than 1500 mL | |
| End point type | Secondary |
| End point timeframe: | |
| Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss. | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2084 | 2066 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 10.3 | 12.7 | | |
| No | 89.7 | 87.3 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Use of an additional uterotonic

| | |
|---|---------------------------------|
| End point title | Use of an additional uterotonic |
| End point description: | |
| Proportion of women requiring additional uterotonic treatment, including sulprostone. | |
| End point type | Secondary |

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2217 | 2206 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 5.9 | 7.2 | | |
| No | 94.1 | 92.8 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Effect of study treatment on secondary endpoints |
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |
| Number of subjects included in analysis | 4423 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.15 |
| Method | Regression, Linear |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | 0.81 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.65 |
| upper limit | 1.03 |

Secondary: Arterial embolization

| | |
|--|-----------------------|
| End point title | Arterial embolization |
| End point description: | |
| Incidence of arterial embolisation and haemostasis surgery for PPH | |
| End point type | Secondary |
| End point timeframe: | |
| Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss. | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2216 | 2206 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 0.6 | 0.3 | | |
| No | 99.4 | 99.7 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Effect of study treatment on secondary endpoints |
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |
| Number of subjects included in analysis | 4422 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.1933 |
| Method | Regression, Linear |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | 2.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 5.66 |

Secondary: Transfusion during hospitalisation

| | |
|--|------------------------------------|
| End point title | Transfusion during hospitalisation |
| End point description: | |
| Incidence of postpartum transfusion | |
| End point type | Secondary |
| End point timeframe: | |
| Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss. | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2221 | 2208 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 1.9 | 1.8 | | |
| No | 98.1 | 98.2 | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Effect of study treatment on secondary endpoints |
| Comparison groups | Modified ITT Placebo v Modified ITT TXA |
| Number of subjects included in analysis | 4429 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.7568 |
| Method | Mixed models analysis |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | 1.07 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.69 |
| upper limit | 1.66 |

Secondary: Total number of red blood cell transfused

| | |
|--|---|
| End point title | Total number of red blood cell transfused |
| End point description: | |
| Number of red blood cell units transfused | |
| End point type | Secondary |
| End point timeframe: | |
| Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss. | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|--------------------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 42 | 39 | | |
| Units: millilitre(s) | | | | |
| arithmetic mean (standard deviation) | 3.1 (± 1.9) | 3.2 (± 2.2) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Delta haemoglobin between day 2 and day 0

| | |
|-----------------|---|
| End point title | Delta haemoglobin between day 2 and day 0 |
|-----------------|---|

End point description:

Mean change in haemoglobin levels (difference between the most recent haemoglobin measured in the 7 days prior to the caesarean section and that at day 2)

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss.

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|--------------------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2088 | 2071 | | |
| Units: g/dL | | | | |
| arithmetic mean (standard deviation) | -1.2 (\pm 1.2) | -1.4 (\pm 1.2) | | |

Statistical analyses

| Statistical analysis title | Effect of study treatment on secondary endpoints |
|---|--|
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |
| Number of subjects included in analysis | 4159 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Linear |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | 0.18 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.11 |
| upper limit | 0.25 |

Secondary: Delta haematocrit between day 2 and day 0

| | |
|-----------------|---|
| End point title | Delta haematocrit between day 2 and day 0 |
|-----------------|---|

End point description:

Mean change in haematocrit levels (difference between the most recent haematocrit measured in the 7 days prior to caesarean section and that at day 2)

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|--------------------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2086 | 2071 | | |
| Units: g/dl | | | | |
| arithmetic mean (standard deviation) | -3.5 (\pm 3.7) | -4.0 (\pm 3.7) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Effect of study treatment on secondary endpoints |
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |
| Number of subjects included in analysis | 4157 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Linear |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | 0.53 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.31 |
| upper limit | 0.75 |

Secondary: Gravimetrically estimated blood loss

| | |
|------------------------|---|
| End point title | Gravimetrically estimated blood loss |
| End point description: | Gravimetrically estimated blood loss is described only in patients who delivered after 07 August 2018 |
| End point type | Secondary |
| End point timeframe: | Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|--------------------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 1774 | 1754 | | |
| Units: millilitre(s) | | | | |
| arithmetic mean (standard deviation) | 688.7 (\pm 886.5) | 719.3 (\pm 919.6) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Effect of study treatment on secondary endpoints |
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |
| Number of subjects included in analysis | 3528 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.214 |
| Method | Regression, Linear |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | -33.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -77.48 |
| upper limit | 11.37 |

Secondary: Total gravimetrically estimated blood loss > 500mL

| | |
|------------------------|---|
| End point title | Total gravimetrically estimated blood loss > 500mL |
| End point description: | Gravimetrically estimated blood loss is described only in patients who delivered after 07 August 2018. |
| End point type | Secondary |
| End point timeframe: | Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 1774 | 1754 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 63.9 | 63.3 | | |
| No | 36.1 | 36.7 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Total gravimetrically estimated blood loss > 1000 mL

| | |
|-----------------|--|
| End point title | Total gravimetrically estimated blood loss > 1000 mL |
|-----------------|--|

End point description:

Gravimetrically estimated blood loss is described only in patients who delivered after 07 August 2018.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 1774 | 1754 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 30.7 | 29.7 | | |
| No | 69.3 | 70.3 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Calculated blood loss

| | |
|-----------------|-----------------------|
| End point title | Calculated blood loss |
|-----------------|-----------------------|

End point description:

Mean estimated blood loss at the end of caesarean section

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Delivered in the immediate aftermath of caesarean birth versus placebo, on other markers of postpartum blood loss

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|--------------------------------------|----------------------|-------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2084 | 2066 | | |
| Units: millilitre(s) | | | | |
| arithmetic mean (standard deviation) | 680.4 (± 748.3) | 787.2 (± 750.0) | | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Effect of study treatment on secondary endpoints |
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |
| Number of subjects included in analysis | 4150 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Linear |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | -107.32 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -151.53 |
| upper limit | -63.11 |

Secondary: Clinically significant postpartum haemorrhage

| | |
|---|---|
| End point title | Clinically significant postpartum haemorrhage |
| End point description: | |
| Incidence of clinically significant postpartum haemorrhage (physician's clinical judgment) | |
| End point type | Secondary |
| End point timeframe: | |
| Delivered in the immediate aftermath of a caesarean birth versus placebo, on other markers of postpartum blood loss | |

| End point values | Modified ITT TXA | Modified ITT Placebo | | |
|-----------------------------|----------------------|----------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 2220 | 2208 | | |
| Units: percent | | | | |
| number (not applicable) | | | | |
| Yes | 13.6 | 14.8 | | |
| No | 86.4 | 85.2 | | |

Statistical analyses

| | |
|-----------------------------------|--|
| Statistical analysis title | Effect of study treatment on secondary endpoints |
| Comparison groups | Modified ITT TXA v Modified ITT Placebo |

| | |
|---|--------------------|
| Number of subjects included in analysis | 4428 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.372 |
| Method | Regression, Linear |
| Parameter estimate | Risk ratio (RR) |
| Point estimate | 0.92 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.08 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Within 12 months after the delivery

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

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| Dictionary name | MedDRA |
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| | |
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| Dictionary version | 19.0 |
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Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | Placebo Group |
|-----------------------|---------------|

Reporting group description: -

| | |
|-----------------------|-----------|
| Reporting group title | TXA Group |
|-----------------------|-----------|

Reporting group description: -

| Serious adverse events | Placebo Group | TXA Group | |
|---|--|------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 345 / 2209 (15.62%) | 342 / 2222 (15.39%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Oncocytoma (10048757) | Additional description: Oncocytoma (10048757) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian neoplasm (10061535) | Additional description: Ovarian neoplasm (10061535) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine leiomyoma (10046798) | Additional description: Uterine leiomyoma (10046798) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|------------------|--|
| Vascular disorders | | | |
| Bleeding varicose vein (10005144) | Additional description: Bleeding varicose vein (10005144) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis (10051055) | Additional description: Deep vein thrombosis (10051055) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemodynamic instability (10052076) | Additional description: Haemodynamic instability (10052076) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haemorrhage (10055798) | Additional description: Haemorrhage (10055798) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypertension (10020772) | Additional description: Hypertension (10020772) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 6 / 2209 (0.27%) | 3 / 2222 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 6 | 1 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypotension (10021097) | Additional description: Hypotension (10021097) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jugular vein thrombosis (10023237) | Additional description: Jugular vein thrombosis (10023237) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic venous thrombosis (10034272) | Additional description: Pelvic venous thrombosis (10034272) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Thrombophlebitis superficial (10043595) | Additional description: Thrombophlebitis superficial (10043595) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical and medical procedures | | | |
| Breast conserving surgery (10076783) | Additional description: Breast conserving surgery (10076783) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Caecectomy (10062859) | Additional description: Caecectomy (10062859) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholecystectomy (10008611) | Additional description: Cholecystectomy (10008611) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eventration repair (10072804) | Additional description: Eventration repair (10072804) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hysterectomy (10021151) | Additional description: Hysterectomy (10021151) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal anastomosis (10057146) | Additional description: Intestinal anastomosis (10057146) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myomectomy (10028634) | Additional description: Myomectomy (10028634) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nephrectomy (10029116) | Additional description: Nephrectomy (10029116) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Proctectomy (10077252) | Additional description: Proctectomy (10077252) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retained placenta operation (10078243) | Additional description: Retained placenta operation (10078243) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 3 / 2222 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Salpingo-oophorectomy (10039464) | Additional description: Salpingo-oophorectomy (10039464) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scar excision (10039583) | Additional description: Scar excision (10039583) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 3 / 2222 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Suture insertion (10052665) | Additional description: Suture insertion (10052665) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transfusion (10066152) | Additional description: Transfusion (10066152) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine dilation and curettage (10057304) | Additional description: Uterine dilation and curettage (10057304) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wedge resection toenail (10047884) | Additional description: Wedge resection toenail (10047884) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Anaphylactoid syndrome of pregnancy (10067010) | Additional description: Anaphylactoid syndrome of pregnancy (10067010) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eclampsia (10014129) | Additional description: Eclampsia (10014129) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gestational hypertension (10070538) | Additional description: Gestational hypertension (10070538) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Jaundice neonatal (10023138) | Additional description: Jaundice neonatal (10023138) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Low birth weight baby (10067508) | Additional description: Low birth weight baby (10067508) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peripartum cardiomyopathy (10049430) | Additional description: Peripartum cardiomyopathy (10049430) | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|--|---|---------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postpartum haemorrhage (10036417) | Additional description: Postpartum haemorrhage (10036417) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 246 / 2209 (11.14%) | 233 / 2222 (10.49%) | |
| occurrences causally related to treatment / all | 3 / 246 | 4 / 233 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retained placenta or membranes (10038758) | Additional description: Retained placenta or membranes (10038758) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 6 / 2209 (0.27%) | 4 / 2222 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Traumatic delivery (10044520) | Additional description: Traumatic delivery (10044520) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine atony (10046763) | Additional description: Uterine atony (10046763) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 11 / 2209 (0.50%) | 8 / 2222 (0.36%) | |
| occurrences causally related to treatment / all | 1 / 11 | 1 / 8 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Weight decrease neonatal (10047894) | Additional description: Weight decrease neonatal (10047894) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Chest discomfort (10008469) | Additional description: Chest discomfort (10008469) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chest pain (10008479) | Additional description: Chest pain (10008479) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperthermia (10020843) | Additional description: Hyperthermia (10020843) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malaise (10025482) | Additional description: Malaise (10025482) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Oedema peripheral (10030124) | Additional description: Oedema peripheral (10030124) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyrexia (10037660) | Additional description: Pyrexia (10037660) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic reaction (10002198) | Additional description: Anaphylactic reaction (10002198) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaphylactic shock (10002199) | Additional description: Anaphylactic shock (10002199) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypersensitivity (10020751) | Additional description: Hypersensitivity (10020751) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reproductive system and breast disorders | | | |
| Endometriosis (10014778) | Additional description: Endometriosis (10014778) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Fibrocystic breast disease (10016621) | Additional description: Fibrocystic breast disease (10016621) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metrorrhagia (10027514) | Additional description: Metrorrhagia (10027514) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ovarian vein thrombosis (10072059) | Additional description: Ovarian vein thrombosis (10072059) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 6 / 2222 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic fluid collection (10065388) | Additional description: Pelvic fluid collection (10065388) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine haematoma (10063875) | Additional description: Uterine haematoma (10063875) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine haemorrhage (10046788) | Additional description: Uterine haemorrhage (10046788) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 3 / 2222 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine pain (10046809) | Additional description: Uterine pain (10046809) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vulvovaginal discomfort (10047786) | Additional description: Vulvovaginal discomfort (10047786) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Acute pulmonary oedema (10001029) | Additional description: Acute pulmonary oedema (10001029) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dyspnoea (10013968) | Additional description: Dyspnoea (10013968) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pleural effusion (10035598) | Additional description: Pleural effusion (10035598) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia aspiration (10035669) | Additional description: Pneumonia aspiration (10035669) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism (10037377) | Additional description: Pulmonary embolism (10037377) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary oedema (10037423) | Additional description: Pulmonary oedema (10037423) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory distress (10038687) | Additional description: Respiratory distress (10038687) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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| Psychiatric disorders | | | |
| Brief psychotic disorder, with postpartum onset (10006362) | Additional description: Brief psychotic disorder, with postpartum onset (10006362) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Depression (10012378) | Additional description: Depression (10012378) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Perinatal depression (10078366) | Additional description: Perinatal depression (10078366) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post-traumatic stress disorder (10036316) | Additional description: Post-traumatic stress disorder (10036316) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Schizoaffective disorder (10039621) | Additional description: Schizoaffective disorder (10039621) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Bile duct stone (10004637) | Additional description: Bile duct stone (10004637) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Biliary colic (10004663) | Additional description: Biliary colic (10004663) | | |

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|---|---|------------------|--|
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholangitis (10008604) | Additional description: Cholangitis (10008604) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis (10008629) | Additional description: Cholelithiasis (10008629) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cholelithiasis migration (10068884) | Additional description: Cholelithiasis migration (10068884) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatocellular injury (10019837) | Additional description: Hepatocellular injury (10019837) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Blood glucose increased (10005557) | Additional description: Blood glucose increased (10005557) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hysteroscopy (10050125) | Additional description: Hysteroscopy (10050125) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory marker increased (10069826) | Additional description: Inflammatory marker increased (10069826) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Arterial injury (10003162) | Additional description: Arterial injury (10003162) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 3 / 2222 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Bladder injury (10061698) | Additional description: Bladder injury (10061698) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Dural tear (10063395) | Additional description: Dural tear (10063395) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body (10070245) | Additional description: Foreign body (10070245) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site haemorrhage (10051100) | Additional description: Incision site haemorrhage (10051100) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|-------------------|--|
| subjects affected / exposed | 11 / 2209 (0.50%) | 5 / 2222 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 11 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Limb injury (10061225) | Additional description: Limb injury (10061225) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Medication error (10027091) | Additional description: Medication error (10027091) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Post procedural haemorrhage (10051077) | Additional description: Post procedural haemorrhage (10051077) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postoperative wound complication (10061468) | Additional description: Postoperative wound complication (10061468) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Procedural haemorrhage (10071229) | Additional description: Procedural haemorrhage (10071229) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 27 / 2209 (1.22%) | 27 / 2222 (1.22%) | |
| occurrences causally related to treatment / all | 0 / 27 | 1 / 27 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Scar (10039580) | Additional description: Scar (10039580) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Subcutaneous haematoma (10042345) | Additional description: Subcutaneous haematoma (10042345) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Surgical procedure repeated (10042618) | Additional description: Surgical procedure repeated (10042618) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ureteric injury (10046405) | Additional description: Ureteric injury (10046405) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine perforation (10046810) | Additional description: Uterine perforation (10046810) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine rupture (10046820) | Additional description: Uterine rupture (10046820) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 3 / 2222 (0.14%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 3 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular injury (10047080) | Additional description: Vascular injury (10047080) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular procedure complication (10057462) | Additional description: Vascular procedure complication (10057462) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Wound evisceration (10054108) | Additional description: Wound evisceration (10054108) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congenital, familial and genetic disorders | | | |
| Urachal abnormality (10066125) | Additional description: Urachal abnormality (10066125) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Cardiac failure (10007554) | Additional description: Cardiac failure (10007554) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardio-respiratory arrest (10007617) | Additional description: Cardio-respiratory arrest (10007617) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Congestive cardiomyopathy (10056370) | Additional description: Congestive cardiomyopathy (10056370) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Palpitations (10033557) | Additional description: Palpitations (10033557) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Altered state of consciousness (10001854) | Additional description: Altered state of consciousness (10001854) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Amnesia (10001949) | Additional description: Amnesia (10001949) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cerebral haematoma (10053942) | Additional description: Cerebral haematoma (10053942) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Epilepsy (10015037) | Additional description: Epilepsy (10015037) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Febrile convulsion (10016284) | Additional description: Febrile convulsion (10016284) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised tonic-clonic seizure (10018100) | Additional description: Generalised tonic-clonic seizure (10018100) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Headache (10019211) | Additional description: Headache (10019211) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 5 / 2209 (0.23%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 2 / 5 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Loss of consciousness (10024855) | Additional description: Loss of consciousness (10024855) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine with aura (10027607) | Additional description: Migraine with aura (10027607) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Motor dysfunction (10061296) | Additional description: Motor dysfunction (10061296) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paraesthesia (10033775) | Additional description: Paraesthesia (10033775) | | |
| alternative assessment type: Non-systematic | | | |

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|--|--|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Posterior reversible encephalopathy syndrome (10071066) | Additional description: Posterior reversible encephalopathy syndrome (10071066) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Reversible cerebral vasoconstriction syndrome (10073240) | Additional description: Reversible cerebral vasoconstriction syndrome (10073240) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 2 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Seizure (10039906) | Additional description: Seizure (10039906) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Anaemia (10002034) | Additional description: Anaemia (10002034) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anaemia of pregnancy (10066468) | Additional description: Anaemia of pregnancy (10066468) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ear and labyrinth disorders | | | |
| Tinnitus (10043882) | Additional description: Tinnitus (10043882) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vertigo (10047340) | Additional description: Vertigo (10047340) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Eye disorders | | | |
| Photopsia (10034962) | Additional description: Photopsia (10034962) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Retinal detachment (10038848) | Additional description: Retinal detachment (10038848) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Visual impairment (10047571) | Additional description: Visual impairment (10047571) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal pain (10000081) | Additional description: Abdominal pain (10000081) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal pain lower (10000084) | Additional description: Abdominal pain lower (10000084) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall haematoma (10067383) | Additional description: Abdominal wall haematoma (10067383) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 6 / 2222 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anal fissure (10002153) | Additional description: Anal fissure (10002153) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Appendiceal mucocoele (10057986) | Additional description: Appendiceal mucocoele (10057986) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ascites (10003445) | Additional description: Ascites (10003445) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Colitis ulcerative (10009900) | Additional description: Colitis ulcerative (10009900) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diarrhoea (10012735) | Additional description: Diarrhoea (10012735) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastritis (10017853) | Additional description: Gastritis (10017853) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematemesis (10018830) | Additional description: Haematemesis (10018830) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hernial eventration (10057391) | Additional description: Hernial eventration (10057391) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ileus (10021328) | Additional description: Ileus (10021328) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Intestinal obstruction (10022687) | Additional description: Intestinal obstruction (10022687) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 4 / 2222 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal obstruction (10062062) | Additional description: Large intestinal obstruction (10062062) | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|--|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nausea (10028813) | | | |
| alternative assessment type: Non-systematic | Additional description: Nausea (10028813) | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pancreatitis acute (10033647) | | | |
| alternative assessment type: Non-systematic | Additional description: Pancreatitis acute (10033647) | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritoneal disorder (10061343) | | | |
| alternative assessment type: Non-systematic | Additional description: Peritoneal disorder (10061343) | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritoneal haemorrhage (10034666) | | | |
| alternative assessment type: Non-systematic | Additional description: Peritoneal haemorrhage (10034666) | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Small intestinal obstruction (10041101) | | | |
| alternative assessment type: Non-systematic | Additional description: Small intestinal obstruction (10041101) | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Strangulated umbilical hernia (10076931) | | | |
| alternative assessment type: Non-systematic | Additional description: Strangulated umbilical hernia (10076931) | | |

| | | | |
|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Umbilical hernia (10045458) | Additional description: Umbilical hernia (10045458) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vomiting (10047700) | Additional description: Vomiting (10047700) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Angioedema (10002424) | Additional description: Angioedema (10002424) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Generalised erythema (10051576) | Additional description: Generalised erythema (10051576) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pruritus (10037087) | Additional description: Pruritus (10037087) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rash (10037844) | Additional description: Rash (10037844) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Acute kidney injury (10069339) | Additional description: Acute kidney injury (10069339) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Anuria (10002847) | Additional description: Anuria (10002847) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Haematuria (10018867) | Additional description: Haematuria (10018867) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal colic (10038419) | Additional description: Renal colic (10038419) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal vein thrombosis (10038548) | Additional description: Renal vein thrombosis (10038548) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary bladder rupture (10046530) | Additional description: Urinary bladder rupture (10046530) | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|---|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinoma (10050091) | Additional description: Urinoma (10050091) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Hyperparathyroidism primary (10020707) | Additional description: Hyperparathyroidism primary (10020707) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Intervertebral disc protrusion (10050296) | Additional description: Intervertebral disc protrusion (10050296) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Neck pain (10028836) | Additional description: Neck pain (10028836) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Abdominal wall abscess (10000099) | Additional description: Abdominal wall abscess (10000099) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 4 / 2222 (0.18%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 4 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Abdominal wall infection (10051254) | Additional description: Abdominal wall infection (10051254) | | |
| alternative assessment type: Non- | | | |

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|---|--|------------------|--|
| systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Breast abscess (10006171) | Additional description: Breast abscess (10006171) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometritis (10014791) | Additional description: Endometritis (10014791) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 6 / 2222 (0.27%) | |
| occurrences causally related to treatment / all | 0 / 4 | 1 / 6 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endometritis decidual (10014792) | Additional description: Endometritis decidual (10014792) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 5 / 2222 (0.23%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 5 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Escherichia infection (10061126) | Additional description: Escherichia infection (10061126) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Genital infection (10048461) | Additional description: Genital infection (10048461) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Incision site abscess (10049660) | Additional description: Incision site abscess (10049660) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 3 / 2209 (0.14%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infected cyst (10058015) | Additional description: Infected cyst (10058015) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lung infection (10061229) | Additional description: Lung infection (10061229) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Lymphangitis (10025226) | Additional description: Lymphangitis (10025226) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Muscle abscess (10049206) | Additional description: Muscle abscess (10049206) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Paronychia (10034016) | Additional description: Paronychia (10034016) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pelvic abscess (10034236) | Additional description: Pelvic abscess (10034236) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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|---|---|------------------|--|
| Perineal abscess (10052457) | Additional description: Perineal abscess (10052457) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Peritonitis (10034674) | Additional description: Peritonitis (10034674) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pneumonia (10035664) | Additional description: Pneumonia (10035664) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Postpartum sepsis (10036422) | Additional description: Postpartum sepsis (10036422) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Puerperal pyrexia (10037294) | Additional description: Puerperal pyrexia (10037294) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis (10037596) | Additional description: Pyelonephritis (10037596) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 1 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute (10037597) | Additional description: Pyelonephritis acute (10037597) | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|--|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sepsis (10040047) | Additional description: Sepsis (10040047) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Septic shock (10040070) | Additional description: Septic shock (10040070) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin infection (10040872) | Additional description: Skin infection (10040872) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Urinary tract infection (10046571) | Additional description: Urinary tract infection (10046571) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Metabolism and nutrition disorders | | | |
| Diabetes mellitus (10012601) | Additional description: Diabetes mellitus (10012601) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypercalcaemia (10020583) | Additional description: Hypercalcaemia (10020583) | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|---|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hyperkalaemia (10020646) | Additional description: Hyperkalaemia (10020646) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia (10020993) | Additional description: Hypoglycaemia (10020993) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hypoglycaemia neonatal (10020994) | Additional description: Hypoglycaemia neonatal (10020994) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Placebo Group | TXA Group | |
|---|--|----------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1206 / 2209 (54.59%) | 1213 / 2222 (54.59%) | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Borderline mucinous tumour of ovary (10073266) | Additional description: Borderline mucinous tumour of ovary (10073266) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Haemangioma of liver (10018821) | Additional description: Haemangioma of liver (10018821) | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|--|---|-----------------------|--|
| subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Uterine leiomyoma (10046798) alternative assessment type: Non-systematic | Additional description: Uterine leiomyoma (10046798) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Vascular disorders | | | |
| Bleeding varicose vein (10005144) alternative assessment type: Non-systematic | Additional description: Bleeding varicose vein (10005144) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Flushing (10016825) alternative assessment type: Non-systematic | Additional description: Flushing (10016825) | | |
| subjects affected / exposed occurrences (all) | 2 / 2209 (0.09%) 2 | 0 / 2222 (0.00%) 0 | |
| Haematoma (10018852) alternative assessment type: Non-systematic | Additional description: Haematoma (10018852) | | |
| subjects affected / exposed occurrences (all) | 8 / 2209 (0.36%) 8 | 2 / 2222 (0.09%) 2 | |
| Haemodynamic instability (10052076) alternative assessment type: Non-systematic | Additional description: Haemodynamic instability (10052076) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Haemorrhage (10055798) alternative assessment type: Non-systematic | Additional description: Haemorrhage (10055798) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Hot flush (10060800) alternative assessment type: Non-systematic | Additional description: Hot flush (10060800) | | |
| subjects affected / exposed occurrences (all) | 4 / 2209 (0.18%) 4 | 7 / 2222 (0.32%) 7 | |
| Hypertension (10020772) alternative assessment type: Non-systematic | Additional description: Hypertension (10020772) | | |

| | | | |
|---|---|-------------------|--|
| subjects affected / exposed | 44 / 2209 (1.99%) | 49 / 2222 (2.21%) | |
| occurrences (all) | 46 | 49 | |
| Hypotension (10021097) | Additional description: Hypotension (10021097) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 29 / 2209 (1.31%) | 22 / 2222 (0.99%) | |
| occurrences (all) | 29 | 22 | |
| Labile blood pressure (10023533) | Additional description: Labile blood pressure (10023533) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Labile hypertension (10049079) | Additional description: Labile hypertension (10049079) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Orthostatic hypotension (10031127) | Additional description: Orthostatic hypotension (10031127) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |
| Pallor (10033546) | Additional description: Pallor (10033546) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Shock (10040560) | Additional description: Shock (10040560) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Thrombophlebitis superficial (10043595) | Additional description: Thrombophlebitis superficial (10043595) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 0 | 4 | |
| Thrombosis (10043607) | Additional description: Thrombosis (10043607) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |

| | | | |
|---|---|------------------|--|
| Varicose vein (10046996) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Varicose vein (10046996) | | |
| | 3 / 2209 (0.14%) | 3 / 2222 (0.14%) | |
| | 3 | 3 | |
| Surgical and medical procedures | Additional description: Caesarean section (10006924) | | |
| | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| | 0 | 1 | |
| | Additional description: General anaesthesia (10018060) | | |
| | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| | 1 | 0 | |
| | Additional description: Haemostasis (10067439) | | |
| | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| | 0 | 1 | |
| | Additional description: Salpingectomy (10039449) | | |
| | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| | 1 | 0 | |
| | Additional description: Amniorrhexis (10051641) | | |
| | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| | 0 | 1 | |
| Pregnancy, puerperium and perinatal conditions | Additional description: Foetal macrosomia (10053700) | | |
| | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| | 0 | 1 | |
| | Additional description: Gestational diabetes (10018209) | | |
| | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| | 0 | 1 | |
| | Additional description: Gestational hypertension (10070538) | | |
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| (10070538) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Postpartum haemorrhage (10036417) | Additional description: Postpartum haemorrhage (10036417) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 40 / 2209 (1.81%) 40 | 36 / 2222 (1.62%) 36 | |
| Pre-eclampsia (10036485) | Additional description: Pre-eclampsia (10036485) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 5 / 2209 (0.23%) 5 | 6 / 2222 (0.27%) 6 | |
| Retained placenta or membranes (10038758) | Additional description: Retained placenta or membranes (10038758) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 2 / 2209 (0.09%) 2 | 2 / 2222 (0.09%) 2 | |
| Uterine atony (10046763) | Additional description: Uterine atony (10046763) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 4 / 2209 (0.18%) 4 | 2 / 2222 (0.09%) 2 | |
| Uterine inversion (10046796) | Additional description: Uterine inversion (10046796) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| General disorders and administration site conditions | | | |
| Asthenia (10003549) | Additional description: Asthenia (10003549) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 2 / 2222 (0.09%) 2 | |
| Chest discomfort (10008469) | Additional description: Chest discomfort (10008469) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 3 / 2209 (0.14%) 3 | 1 / 2222 (0.05%) 1 | |
| Chest pain (10008479) | Additional description: Chest pain (10008479) | | |

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| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 7 / 2222 (0.32%) | |
| occurrences (all) | 3 | 7 | |
| Chills (10008531) | Additional description: Chills (10008531) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 6 / 2222 (0.27%) | |
| occurrences (all) | 1 | 6 | |
| Crepitations (10011376) | Additional description: Crepitations (10011376) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Drug intolerance (10061822) | Additional description: Drug intolerance (10061822) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Face oedema (10016029) | Additional description: Face oedema (10016029) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Fatigue (10016256) | Additional description: Fatigue (10016256) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Feeling abnormal (10016322) | Additional description: Feeling abnormal (10016322) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Generalised oedema (10018092) | Additional description: Generalised oedema (10018092) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Hernia (10019909) | Additional description: Hernia (10019909) | | |
| alternative assessment type: Non-systematic | | | |

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| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Hyperthermia (10020843) | Additional description: Hyperthermia (10020843) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 10 / 2209 (0.45%) | 9 / 2222 (0.41%) | |
| occurrences (all) | 10 | 9 | |
| Hypothermia (10021113) | Additional description: Hypothermia (10021113) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Inflammation (10061218) | Additional description: Inflammation (10061218) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Injection site haematoma (10022066) | Additional description: Injection site haematoma (10022066) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Injection site pain (10022086) | Additional description: Injection site pain (10022086) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Injection site paraesthesia (10022088) | Additional description: Injection site paraesthesia (10022088) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Localised oedema (10048961) | Additional description: Localised oedema (10048961) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Malaise (10025482) | Additional description: Malaise (10025482) | | |
| alternative assessment type: Non-systematic | | | |

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| subjects affected / exposed | 21 / 2209 (0.95%) | 13 / 2222 (0.59%) | |
| occurrences (all) | 21 | 13 | |
| Oedema (10030095) | Additional description: Oedema (10030095) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 11 / 2209 (0.50%) | 16 / 2222 (0.72%) | |
| occurrences (all) | 11 | 16 | |
| Oedema peripheral (10030124) | Additional description: Oedema peripheral (10030124) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 129 / 2209 (5.84%) | 133 / 2222 (5.99%) | |
| occurrences (all) | 131 | 135 | |
| Pain (10033371) | Additional description: Pain (10033371) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 4 / 2222 (0.18%) | |
| occurrences (all) | 4 | 4 | |
| Pyrexia (10037660) | Additional description: Pyrexia (10037660) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 7 / 2209 (0.32%) | 18 / 2222 (0.81%) | |
| occurrences (all) | 7 | 19 | |
| Sense of oppression (10040007) | Additional description: Sense of oppression (10040007) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Swelling (10042674) | Additional description: Swelling (10042674) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Immune system disorders | | | |
| Hypersensitivity (10020751) | Additional description: Hypersensitivity (10020751) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 2 | 2 | |
| Reproductive system and breast disorders | | | |
| Breast cyst (10006220) | Additional description: Breast cyst (10006220) | | |
| alternative assessment type: Non-systematic | | | |

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| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Breast engorgement (10006240) | Additional description: Breast engorgement (10006240) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Breast mass (10006272) | Additional description: Breast mass (10006272) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Dyspareunia (10013941) | Additional description: Dyspareunia (10013941) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Female genital tract fistula (10061149) | Additional description: Female genital tract fistula (10061149) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Galactoceles (10017590) | Additional description: Galactoceles (10017590) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Lactation disorder (10061261) | Additional description: Lactation disorder (10061261) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 2 | 2 | |
| Metrorrhagia (10027514) | Additional description: Metrorrhagia (10027514) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 4 | 1 | |
| Nipple disorder (10029417) | Additional description: Nipple disorder (10029417) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |

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| Ovarian cyst (10033132) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Ovarian cyst (10033132) | | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Pelvic pain (10034263) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Pelvic pain (10034263) | | |
| | 1 / 2209 (0.05%) 1 | 2 / 2222 (0.09%) 2 | |
| Threatened uterine rupture (10080427) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Threatened uterine rupture (10080427) | | |
| | 3 / 2209 (0.14%) 3 | 2 / 2222 (0.09%) 2 | |
| Uterine haemorrhage (10046788) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Uterine haemorrhage (10046788) | | |
| | 2 / 2209 (0.09%) 2 | 4 / 2222 (0.18%) 4 | |
| Uterine pain (10046809) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Uterine pain (10046809) | | |
| | 2 / 2209 (0.09%) 2 | 0 / 2222 (0.00%) 0 | |
| Uterine spasm (10046823) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Uterine spasm (10046823) | | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Vaginal discharge (10046901) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Vaginal discharge (10046901) | | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Vulvovaginal pruritus (10056530) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Vulvovaginal pruritus (10056530) | | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |

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| Asthma (10003553) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Asthma (10003553) | |
| | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) |
| | 1 | 0 |
| Choking sensation (10008590) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Choking sensation (10008590) | |
| | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) |
| | 0 | 1 |
| Cough (10011224) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Cough (10011224) | |
| | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) |
| | 1 | 3 |
| Dyspnoea (10013968) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Dyspnoea (10013968) | |
| | 5 / 2209 (0.23%) | 4 / 2222 (0.18%) |
| | 5 | 4 |
| Emphysema (10014561) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Emphysema (10014561) | |
| | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) |
| | 0 | 1 |
| Oropharyngeal pain (10068319) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Oropharyngeal pain (10068319) | |
| | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) |
| | 1 | 0 |
| Productive cough (10036790) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Productive cough (10036790) | |
| | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) |
| | 1 | 0 |
| Rales (10037833) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Rales (10037833) | |
| | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) |
| | 1 | 0 |
| Respiratory distress (10038687) alternative assessment type: Non-systematic | Additional description: Respiratory distress (10038687) | |
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| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Rhinorrhoea (10039101) | Additional description: Rhinorrhoea (10039101) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Throat irritation (10043521) | Additional description: Throat irritation (10043521) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Wheezing (10047924) | Additional description: Wheezing (10047924) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Psychiatric disorders | | | |
| Anxiety (10002855) | Additional description: Anxiety (10002855) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 7 / 2209 (0.32%) 7 | 4 / 2222 (0.18%) 4 | |
| Depressed mood (10012374) | Additional description: Depressed mood (10012374) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Depression (10012378) | Additional description: Depression (10012378) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 2 / 2209 (0.09%) 2 | 1 / 2222 (0.05%) 1 | |
| Dissociation (10013457) | Additional description: Dissociation (10013457) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Emotional distress (10049119) | Additional description: Emotional distress (10049119) | | |
| alternative assessment type: Non-systematic | | | |

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| subjects affected / exposed occurrences (all) | 9 / 2209 (0.41%) 9 | 8 / 2222 (0.36%) 8 | |
| Hallucination (10019063) alternative assessment type: Non-systematic | Additional description: Hallucination (10019063) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Hallucination, visual (10019075) alternative assessment type: Non-systematic | Additional description: Hallucination, visual (10019075) | | |
| subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Insomnia (10022437) alternative assessment type: Non-systematic | Additional description: Insomnia (10022437) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Mental disorder (10061284) alternative assessment type: Non-systematic | Additional description: Mental disorder (10061284) | | |
| subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Perinatal depression (10078366) alternative assessment type: Non-systematic | Additional description: Perinatal depression (10078366) | | |
| subjects affected / exposed occurrences (all) | 4 / 2209 (0.18%) 4 | 6 / 2222 (0.27%) 6 | |
| Sleep disorder (10040984) alternative assessment type: Non-systematic | Additional description: Sleep disorder (10040984) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Hepatobiliary disorders | | | |
| Cholelithiasis (10008629) alternative assessment type: Non-systematic | Additional description: Cholelithiasis (10008629) | | |
| subjects affected / exposed occurrences (all) | 2 / 2209 (0.09%) 2 | 2 / 2222 (0.09%) 2 | |
| Hepatocellular injury (10019837) alternative assessment type: Non-systematic | Additional description: Hepatocellular injury (10019837) | | |
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| subjects affected / exposed | 6 / 2209 (0.27%) | 10 / 2222 (0.45%) | |
| occurrences (all) | 6 | 10 | |
| Investigations | | | |
| Activated partial thromboplastin time prolonged (10000636) | Additional description: Activated partial thromboplastin time prolonged (10000636) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Antinuclear antibody (10002807) | Additional description: Antinuclear antibody (10002807) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Blood alkaline phosphatase increased (10059570) | Additional description: Blood alkaline phosphatase increased (10059570) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood creatinine increased (10005483) | Additional description: Blood creatinine increased (10005483) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |
| Blood culture positive (10005488) | Additional description: Blood culture positive (10005488) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Blood glucose fluctuation (10049803) | Additional description: Blood glucose fluctuation (10049803) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blood uric acid increased (10005861) | Additional description: Blood uric acid increased (10005861) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| C-reactive protein increased (10006825) | Additional description: C-reactive protein increased (10006825) | | |
| alternative assessment type: Non- | | | |

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| systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |
| Citrobacter test positive (10069963) | Additional description: Citrobacter test positive (10069963) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Electrocardiogram abnormal (10014363) | Additional description: Electrocardiogram abnormal (10014363) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Haemoglobin decreased (10018884) | Additional description: Haemoglobin decreased (10018884) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 5 / 2209 (0.23%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 5 | 2 | |
| Homans' sign positive (10051031) | Additional description: Homans' sign positive (10051031) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Liver function test abnormal (10024690) | Additional description: Liver function test abnormal (10024690) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 2 | |
| Oxygen saturation decreased (10033318) | Additional description: Oxygen saturation decreased (10033318) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 1 | 2 | |
| Proteus test positive (10070134) | Additional description: Proteus test positive (10070134) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Renal function test abnormal (10061480) | Additional description: Renal function test abnormal (10061480) | | |
| alternative assessment type: Non-systematic | | | |

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| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Smear cervix abnormal (10041206) | Additional description: Smear cervix abnormal (10041206) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Transaminases increased (10054889) | Additional description: Transaminases increased (10054889) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Injury, poisoning and procedural complications | | | |
| Anaesthetic complication (10060938) | Additional description: Anaesthetic complication (10060938) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Arterial injury (10003162) | Additional description: Arterial injury (10003162) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 3 | 3 | |
| Bladder injury (10061698) | Additional description: Bladder injury (10061698) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 4 / 2222 (0.18%) | |
| occurrences (all) | 3 | 4 | |
| Dural tear (10063395) | Additional description: Dural tear (10063395) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 1 | 2 | |
| Fall (10016173) | Additional description: Fall (10016173) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Head injury (10019196) | Additional description: Head injury (10019196) | | |
| alternative assessment type: Non-systematic | | | |

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|---|--|-------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Incision site discharge (10082296) | Additional description: Incision site discharge (10082296) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 11 / 2209 (0.50%) | 6 / 2222 (0.27%) | |
| occurrences (all) | 11 | 6 | |
| Incision site haematoma (10059241) | Additional description: Incision site haematoma (10059241) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 24 / 2209 (1.09%) | 12 / 2222 (0.54%) | |
| occurrences (all) | 24 | 12 | |
| Incision site haemorrhage (10051100) | Additional description: Incision site haemorrhage (10051100) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 10 / 2209 (0.45%) | 6 / 2222 (0.27%) | |
| occurrences (all) | 10 | 6 | |
| Incision site hypoaesthesia (10069386) | Additional description: Incision site hypoaesthesia (10069386) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Incision site oedema (10065614) | Additional description: Incision site oedema (10065614) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 1 | 3 | |
| Incision site pain (10058043) | Additional description: Incision site pain (10058043) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Joint dislocation (10023204) | Additional description: Joint dislocation (10023204) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Ligament sprain (10024453) | Additional description: Ligament sprain (10024453) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|-------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Meniscus injury (10072970) | Additional description: Meniscus injury (10072970) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Post lumbar puncture syndrome (10060854) | Additional description: Post lumbar puncture syndrome (10060854) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 4 / 2222 (0.18%) | |
| occurrences (all) | 2 | 4 | |
| Post procedural urine leak (10057587) | Additional description: Post procedural urine leak (10057587) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Postoperative wound complication (10061468) | Additional description: Postoperative wound complication (10061468) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 36 / 2209 (1.63%) | 28 / 2222 (1.26%) | |
| occurrences (all) | 36 | 28 | |
| Procedural haemorrhage (10071229) | Additional description: Procedural haemorrhage (10071229) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 8 / 2209 (0.36%) | 7 / 2222 (0.32%) | |
| occurrences (all) | 8 | 7 | |
| Procedural hypotension (10062300) | Additional description: Procedural hypotension (10062300) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 2 | 2 | |
| Procedural pain (10064882) | Additional description: Procedural pain (10064882) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Reproductive tract procedural complication (10081324) | Additional description: Reproductive tract procedural complication (10081324) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 1 | 3 | |
| Scar (10039580) | Additional description: Scar (10039580) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 8 / 2209 (0.36%) | 7 / 2222 (0.32%) | |
| occurrences (all) | 8 | 7 | |
| Surgical procedure repeated (10042618) | Additional description: Surgical procedure repeated (10042618) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Transfusion-associated dyspnoea (10072266) | Additional description: Transfusion-associated dyspnoea (10072266) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Uterine rupture (10046820) | Additional description: Uterine rupture (10046820) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 4 / 2222 (0.18%) | |
| occurrences (all) | 1 | 4 | |
| Wound (10052428) | Additional description: Wound (10052428) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Wound secretion (10048629) | Additional description: Wound secretion (10048629) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Wrong technique in product usage process (10076573) | Additional description: Wrong technique in product usage process (10076573) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Congenital, familial and genetic disorders | | | |

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|--|---|-----------------------|-----------------------|--|
| Thalassaemia (10043388) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Thalassaemia (10043388) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Cardiac disorders | | | | |
| Atrioventricular block (10003671) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Atrioventricular block (10003671) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Bradycardia (10006093) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Bradycardia (10006093) | 2 / 2209 (0.09%) 2 | 4 / 2222 (0.18%) 4 | |
| Extrasystoles (10015856) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Extrasystoles (10015856) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Palpitations (10033557) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Palpitations (10033557) | 1 / 2209 (0.05%) 1 | 3 / 2222 (0.14%) 3 | |
| Sinus tachycardia (10040752) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Sinus tachycardia (10040752) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Tachycardia (10043071) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Tachycardia (10043071) | 7 / 2209 (0.32%) 7 | 8 / 2222 (0.36%) 8 | |
| Nervous system disorders | | | | |
| Carpal tunnel syndrome (10007697) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Carpal tunnel syndrome (10007697) | 2 / 2209 (0.09%) 2 | 1 / 2222 (0.05%) 1 | |
| Cervical radiculopathy (10050217) | Additional description: Cervical radiculopathy (10050217) | | | |

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| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Dizziness postural (10013578) | Additional description: Dizziness postural (10013578) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Dysarthria (10013887) | Additional description: Dysarthria (10013887) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Headache (10019211) | Additional description: Headache (10019211) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 46 / 2209 (2.08%) | 44 / 2222 (1.98%) | |
| occurrences (all) | 47 | 45 | |
| Loss of consciousness (10024855) | Additional description: Loss of consciousness (10024855) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Migraine (10027599) | Additional description: Migraine (10027599) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 5 / 2209 (0.23%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 5 | 0 | |
| Migraine with aura (10027607) | Additional description: Migraine with aura (10027607) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Motor dysfunction (10061296) | Additional description: Motor dysfunction (10061296) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Paraesthesia (10033775) | Additional description: Paraesthesia (10033775) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|--------------------|--|
| subjects affected / exposed | 5 / 2209 (0.23%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 5 | 3 | |
| Presyncope (10036653) | Additional description: Presyncope (10036653) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 9 / 2209 (0.41%) | 6 / 2222 (0.27%) | |
| occurrences (all) | 9 | 6 | |
| Sciatica (10039674) | Additional description: Sciatica (10039674) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Sensory disturbance (10040026) | Additional description: Sensory disturbance (10040026) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Syncope (10042772) | Additional description: Syncope (10042772) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Tremor (10044565) | Additional description: Tremor (10044565) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 8 / 2209 (0.36%) | 5 / 2222 (0.23%) | |
| occurrences (all) | 8 | 5 | |
| Blood and lymphatic system disorders | | | |
| Anaemia (10002034) | Additional description: Anaemia (10002034) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 242 / 2209 (10.96%) | 212 / 2222 (9.54%) | |
| occurrences (all) | 242 | 212 | |
| Anaemia of pregnancy (10066468) | Additional description: Anaemia of pregnancy (10066468) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 69 / 2209 (3.12%) | 48 / 2222 (2.16%) | |
| occurrences (all) | 70 | 48 | |
| Coagulopathy (10009802) | Additional description: Coagulopathy (10009802) | | |
| alternative assessment type: Non-systematic | | | |

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| subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Hyperfibrinogenaemia (10051124) alternative assessment type: Non-systematic | Additional description: Hyperfibrinogenaemia (10051124) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Normocytic anaemia (10029784) alternative assessment type: Non-systematic | Additional description: Normocytic anaemia (10029784) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Pancytopenia (10033661) alternative assessment type: Non-systematic | Additional description: Pancytopenia (10033661) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Thrombocytopenia (10043554) alternative assessment type: Non-systematic | Additional description: Thrombocytopenia (10043554) | | |
| subjects affected / exposed occurrences (all) | 3 / 2209 (0.14%) 3 | 7 / 2222 (0.32%) 7 | |
| Thrombocytosis (10043563) alternative assessment type: Non-systematic | Additional description: Thrombocytosis (10043563) | | |
| subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Ear and labyrinth disorders | | | |
| Tinnitus (10043882) alternative assessment type: Non-systematic | Additional description: Tinnitus (10043882) | | |
| subjects affected / exposed occurrences (all) | 4 / 2209 (0.18%) 4 | 6 / 2222 (0.27%) 6 | |
| Tympanic membrane perforation (10045210) alternative assessment type: Non-systematic | Additional description: Tympanic membrane perforation (10045210) | | |
| subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Vertigo (10047340) alternative assessment type: Non-systematic | Additional description: Vertigo (10047340) | | |
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| subjects affected / exposed | 102 / 2209 (4.62%) | 112 / 2222 (5.04%) | |
| occurrences (all) | 104 | 113 | |
| Eye disorders | | | |
| Chalazion (10008388) | Additional description: Chalazion (10008388) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Eyelid oedema (10015993) | Additional description: Eyelid oedema (10015993) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Photophobia (10034960) | Additional description: Photophobia (10034960) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 0 | 2 | |
| Photopsia (10034962) | Additional description: Photopsia (10034962) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 8 / 2222 (0.36%) | |
| occurrences (all) | 3 | 8 | |
| Vision blurred (10047513) | Additional description: Vision blurred (10047513) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |
| Visual impairment (10047571) | Additional description: Visual impairment (10047571) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Gastrointestinal disorders | | | |
| Abdominal distension (10000060) | Additional description: Abdominal distension (10000060) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 5 / 2209 (0.23%) | 4 / 2222 (0.18%) | |
| occurrences (all) | 5 | 4 | |
| Abdominal pain (10000081) | Additional description: Abdominal pain (10000081) | | |
| alternative assessment type: Non-systematic | | | |

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| subjects affected / exposed | 5 / 2209 (0.23%) | 8 / 2222 (0.36%) | |
| occurrences (all) | 5 | 8 | |
| Abdominal pain lower (10000084) | Additional description: Abdominal pain lower (10000084) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |
| Abdominal pain upper (10000087) | Additional description: Abdominal pain upper (10000087) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 6 / 2222 (0.27%) | |
| occurrences (all) | 0 | 6 | |
| Abdominal wall haematoma (10067383) | Additional description: Abdominal wall haematoma (10067383) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 46 / 2209 (2.08%) | 33 / 2222 (1.49%) | |
| occurrences (all) | 46 | 33 | |
| Constipation (10010774) | Additional description: Constipation (10010774) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 105 / 2209 (4.75%) | 115 / 2222 (5.18%) | |
| occurrences (all) | 106 | 115 | |
| Diarrhoea (10012735) | Additional description: Diarrhoea (10012735) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 13 / 2209 (0.59%) | 8 / 2222 (0.36%) | |
| occurrences (all) | 13 | 8 | |
| Dyspepsia (10013946) | Additional description: Dyspepsia (10013946) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Flatulence (10016766) | Additional description: Flatulence (10016766) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |
| Gastrointestinal pain (10017999) | Additional description: Gastrointestinal pain (10017999) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |

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| Gastrooesophageal reflux disease (10017885) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Gastrooesophageal reflux disease (10017885) | |
| | 1 / 2209 (0.05%) 1 | 2 / 2222 (0.09%) 2 |
| | | |
| Haemorrhoids (10019022) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Haemorrhoids (10019022) | |
| | 9 / 2209 (0.41%) 9 | 5 / 2222 (0.23%) 5 |
| | | |
| Haemorrhoids thrombosed (10019023) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Haemorrhoids thrombosed (10019023) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| | | |
| Hypoaesthesia oral (10057371) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Hypoaesthesia oral (10057371) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| | | |
| Intestinal mass (10059017) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Intestinal mass (10059017) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| | | |
| Nausea (10028813) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Nausea (10028813) | |
| | 475 / 2209 (21.50%) 502 | 529 / 2222 (23.81%) 545 |
| | | |
| Obstruction gastric (10029957) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Obstruction gastric (10029957) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| | | |
| Toothache (10044055) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Toothache (10044055) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| | | |
| Umbilical hernia (10045458) alternative assessment type: Non- | Additional description: Umbilical hernia (10045458) | |
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| systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Vomiting (10047700) | Additional description: Vomiting (10047700) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 254 / 2209 (11.50%) | 299 / 2222 (13.46%) | |
| occurrences (all) | 264 | 316 | |
| Skin and subcutaneous tissue disorders | | | |
| Acne (10000496) | Additional description: Acne (10000496) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Blister (10005191) | Additional description: Blister (10005191) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Dermatitis (10012431) | Additional description: Dermatitis (10012431) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Dermatitis allergic (10012434) | Additional description: Dermatitis allergic (10012434) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Dermatitis contact (10012442) | Additional description: Dermatitis contact (10012442) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| Ecchymosis (10014080) | Additional description: Ecchymosis (10014080) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 1 | 2 | |
| Eczema (10014184) | Additional description: Eczema (10014184) | | |
| alternative assessment type: Non-systematic | | | |

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|---|---|-------------------|--|
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Erythema (10015150) | Additional description: Erythema (10015150) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 5 / 2222 (0.23%) | |
| occurrences (all) | 4 | 5 | |
| Hyperhidrosis (10020642) | Additional description: Hyperhidrosis (10020642) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 5 / 2209 (0.23%) | 4 / 2222 (0.18%) | |
| occurrences (all) | 5 | 4 | |
| Pruritus (10037087) | Additional description: Pruritus (10037087) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 17 / 2209 (0.77%) | 17 / 2222 (0.77%) | |
| occurrences (all) | 17 | 17 | |
| Pruritus generalised (10052576) | Additional description: Pruritus generalised (10052576) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 4 | 2 | |
| Rash (10037844) | Additional description: Rash (10037844) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 6 / 2222 (0.27%) | |
| occurrences (all) | 3 | 6 | |
| Rash erythematous (10037855) | Additional description: Rash erythematous (10037855) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Rash pruritic (10037884) | Additional description: Rash pruritic (10037884) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Scar pain (10049002) | Additional description: Scar pain (10049002) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 5 / 2209 (0.23%) | 10 / 2222 (0.45%) | |
| occurrences (all) | 5 | 10 | |

| | | | |
|--|--|------------------------|--|
| Skin maceration (10048625) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Skin maceration (10048625) | | |
| | 1 / 2209 (0.05%) 1 | 1 / 2222 (0.05%) 1 | |
| | | | |
| Subcutaneous emphysema (10042344) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Subcutaneous emphysema (10042344) | | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| | | | |
| Urticaria (10046735) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Urticaria (10046735) | | |
| | 2 / 2209 (0.09%) 2 | 1 / 2222 (0.05%) 1 | |
| | | | |
| Renal and urinary disorders | | | |
| | Additional description: Acute kidney injury (10069339) | | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| | | | |
| | Additional description: Dysuria (10013990) | | |
| | 9 / 2209 (0.41%) 9 | 9 / 2222 (0.41%) 10 | |
| | | | |
| | Additional description: Haematuria (10018867) | | |
| | 2 / 2209 (0.09%) 2 | 1 / 2222 (0.05%) 1 | |
| | | | |
| | Additional description: Hypotonic urinary bladder (10058914) | | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| | | | |
| Nephrolithiasis (10029148) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Nephrolithiasis (10029148) | | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| | | | |
| Prerenal failure (10072370) | Additional description: Prerenal failure (10072370) | | |

| | | | |
|---|---|---------------------------|--|
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Proteinuria (10037032) | Additional description: Proteinuria (10037032) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 2 / 2222 (0.09%) 2 | |
| Renal colic (10038419) | Additional description: Renal colic (10038419) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Renal failure (10038435) | Additional description: Renal failure (10038435) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Stress urinary incontinence (10066218) | Additional description: Stress urinary incontinence (10066218) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Tubulointerstitial nephritis (10048302) | Additional description: Tubulointerstitial nephritis (10048302) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Urinary bladder rupture (10046530) | Additional description: Urinary bladder rupture (10046530) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Urinary retention (10046555) | Additional description: Urinary retention (10046555) | | |
| alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 170 / 2209 (7.70%) 170 | 161 / 2222 (7.25%) 161 | |
| Endocrine disorders | | | |

| | | |
|---|---|-------------------------|
| Hyperthyroidism (10020850) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Hyperthyroidism (10020850) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | |
| | Additional description: Arthralgia (10003239) | |
| Arthralgia (10003239) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 2 / 2222 (0.09%) 2 |
| | Additional description: Axillary mass (10049021) | |
| Axillary mass (10049021) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| | Additional description: Back pain (10003988) | |
| Back pain (10003988) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 5 / 2209 (0.23%) 5 | 12 / 2222 (0.54%) 12 |
| | Additional description: Coccydynia (10009829) | |
| Coccydynia (10009829) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 1 / 2209 (0.05%) 1 | 1 / 2222 (0.05%) 1 |
| | Additional description: Diastasis recti abdominis (10073169) | |
| Diastasis recti abdominis (10073169) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 3 / 2209 (0.14%) 3 | 0 / 2222 (0.00%) 0 |
| | Additional description: Fistula (10016717) | |
| Fistula (10016717) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 |
| | Additional description: Flank pain (10016750) | |
| Flank pain (10016750) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | 3 / 2209 (0.14%) 3 | 1 / 2222 (0.05%) 1 |
| | Additional description: Intervertebral disc protrusion (10050296) | |
| Intervertebral disc protrusion (10050296) | | |

| | | | |
|---|---|------------------|--|
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Muscle spasms (10028334) | Additional description: Muscle spasms (10028334) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 3 | 0 | |
| Musculoskeletal chest pain (10050819) | Additional description: Musculoskeletal chest pain (10050819) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 1 | 2 | |
| Musculoskeletal pain (10028391) | Additional description: Musculoskeletal pain (10028391) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 4 / 2209 (0.18%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 4 | 3 | |
| Myositis (10028653) | Additional description: Myositis (10028653) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Neck pain (10028836) | Additional description: Neck pain (10028836) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 4 / 2222 (0.18%) | |
| occurrences (all) | 1 | 4 | |
| Pain in extremity (10033425) | Additional description: Pain in extremity (10033425) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 5 / 2209 (0.23%) | 5 / 2222 (0.23%) | |
| occurrences (all) | 6 | 5 | |
| Polyarthrititis (10036030) | Additional description: Polyarthrititis (10036030) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Infections and infestations | | | |
| Abdominal wall abscess (10000099) | Additional description: Abdominal wall abscess (10000099) | | |
| alternative assessment type: Non-systematic | | | |

| | | | |
|---|--|------------------|--|
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| ----- | | | |
| Acarodermatitis (10063409) | Additional description: Acarodermatitis (10063409) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| ----- | | | |
| Bacterial disease carrier (10004017) | Additional description: Bacterial disease carrier (10004017) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| ----- | | | |
| Bacterial vaginosis (10004055) | Additional description: Bacterial vaginosis (10004055) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| ----- | | | |
| Bronchitis (10006451) | Additional description: Bronchitis (10006451) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| ----- | | | |
| Cystitis (10011781) | Additional description: Cystitis (10011781) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 3 / 2209 (0.14%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 3 | 1 | |
| ----- | | | |
| Cystitis bacterial (10065198) | Additional description: Cystitis bacterial (10065198) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 1 | 1 | |
| ----- | | | |
| Cystitis escherichia (10011790) | Additional description: Cystitis escherichia (10011790) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| ----- | | | |
| Dermatophytosis (10012504) | Additional description: Dermatophytosis (10012504) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |

| | | |
|---|--|-----------------------|
| Dermatophytosis of nail (10012511) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Dermatophytosis of nail (10012511) | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 |
| Ear infection (10014011) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Ear infection (10014011) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| Endometritis (10014791) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Endometritis (10014791) | |
| | 2 / 2209 (0.09%) 2 | 8 / 2222 (0.36%) 8 |
| Endometritis decidual (10014792) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Endometritis decidual (10014792) | |
| | 1 / 2209 (0.05%) 1 | 2 / 2222 (0.09%) 2 |
| Fungal infection (10017533) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Fungal infection (10017533) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| Incision site abscess (10049660) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Incision site abscess (10049660) | |
| | 2 / 2209 (0.09%) 2 | 2 / 2222 (0.09%) 2 |
| Influenza (10022000) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Influenza (10022000) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| Lung infection (10061229) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Lung infection (10061229) | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 |
| Lymphangitis (10025226) alternative assessment type: Non-systematic | Additional description: Lymphangitis (10025226) | |
| | | |

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|---|---|------------------|--|
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Mastitis (10026883) | Additional description: Mastitis (10026883) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 2 | 3 | |
| Nasal herpes (10074936) | Additional description: Nasal herpes (10074936) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) | |
| occurrences (all) | 0 | 2 | |
| Nasopharyngitis (10028810) | Additional description: Nasopharyngitis (10028810) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Oral herpes (10067152) | Additional description: Oral herpes (10067152) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 3 / 2222 (0.14%) | |
| occurrences (all) | 0 | 3 | |
| Pilonidal cyst (10035043) | Additional description: Pilonidal cyst (10035043) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 2 | 0 | |
| Pneumonia (10035664) | Additional description: Pneumonia (10035664) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 0 | 1 | |
| Puerperal pyrexia (10037294) | Additional description: Puerperal pyrexia (10037294) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) | |
| occurrences (all) | 1 | 0 | |
| Purulent discharge (10037569) | Additional description: Purulent discharge (10037569) | | |
| alternative assessment type: Non-systematic | | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 1 / 2222 (0.05%) | |
| occurrences (all) | 2 | 1 | |

| | | | |
|--|---|-------------------------|--|
| Pyelonephritis (10037596) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Pyelonephritis (10037596) | | |
| | 1 / 2209 (0.05%) 1 | 2 / 2222 (0.09%) 2 | |
| Sinusitis (10040753) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Sinusitis (10040753) | | |
| | 1 / 2209 (0.05%) 1 | 0 / 2222 (0.00%) 0 | |
| Skin infection (10040872) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Skin infection (10040872) | | |
| | 3 / 2209 (0.14%) 3 | 4 / 2222 (0.18%) 4 | |
| Tonsillitis (10044008) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Tonsillitis (10044008) | | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Urinary tract infection (10046571) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Urinary tract infection (10046571) | | |
| | 4 / 2209 (0.18%) 4 | 10 / 2222 (0.45%) 10 | |
| Vaginal infection (10046914) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Vaginal infection (10046914) | | |
| | 1 / 2209 (0.05%) 1 | 1 / 2222 (0.05%) 1 | |
| Vaginitis gardnerella (10046957) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Vaginitis gardnerella (10046957) | | |
| | 1 / 2209 (0.05%) 1 | 1 / 2222 (0.05%) 1 | |
| Vulvovaginal mycotic infection (10064899) alternative assessment type: Non-systematic subjects affected / exposed occurrences (all) | Additional description: Vulvovaginal mycotic infection (10064899) | | |
| | 0 / 2209 (0.00%) 0 | 1 / 2222 (0.05%) 1 | |
| Metabolism and nutrition disorders | | | |

| | | |
|---|--|------------------|
| Hyperinsulinaemic hypoglycaemia (10077216) | Additional description: Hyperinsulinaemic hypoglycaemia (10077216) | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) |
| occurrences (all) | 1 | 0 |
| Hyperkalaemia (10020646) | Additional description: Hyperkalaemia (10020646) | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) |
| occurrences (all) | 1 | 0 |
| Hypoglycaemia (10020993) | Additional description: Hypoglycaemia (10020993) | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 2 / 2209 (0.09%) | 2 / 2222 (0.09%) |
| occurrences (all) | 2 | 2 |
| Hypokalaemia (10021015) | Additional description: Hypokalaemia (10021015) | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 2 / 2222 (0.09%) |
| occurrences (all) | 0 | 2 |
| Hypovitaminosis (10021135) | Additional description: Hypovitaminosis (10021135) | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 1 / 2209 (0.05%) | 0 / 2222 (0.00%) |
| occurrences (all) | 1 | 0 |
| Hypovolaemia (10021137) | Additional description: Hypovolaemia (10021137) | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) |
| occurrences (all) | 0 | 1 |
| Obesity (10029883) | Additional description: Obesity (10029883) | |
| alternative assessment type: Non-systematic | | |
| subjects affected / exposed | 0 / 2209 (0.00%) | 1 / 2222 (0.05%) |
| occurrences (all) | 0 | 1 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 06 December 2017 | <ol style="list-style-type: none">1. Additional information in participant information letter upon request of CNIL (French Data Protection Authority)2. Modification of the circuit of centralization of the nominative data3. Addition of a investigating site (CHU de Caen) |
| 15 February 2018 | <ol style="list-style-type: none">1. The 4-hour delay after the injection before the start of breastfeeding is removed2. Comprehensive safety of all serious adverse events is reduced to the 1st month of participation. Only serious adverse events will then be reported.3. A secondary medico-economic objective is added: calculation of the incremental cost/effectiveness ratio of TXA versus placebo from the point of view of health insurance4. The inclusion criterion 'CBC within 3 days prior to caesarean section' becomes '...within 7 days prior to caesarean section'.5. Change of the principal investigator of Sites CHU de Rennes and CHU de Toulouse6. Addition of two investigating sites : CHI de Créteil and CH de Pau |
| 18 June 2018 | <ol style="list-style-type: none">1. Changing the way centralized data is transmitted2. The addition of a TRAAP 2 presentation poster for waiting rooms.3. Addition of two investigating sites : CHU de Poitiers et CHU de Strasbourg (second site)4. Modification of the possibility of participating in another study for TRAPP 2 participant |
| 09 January 2019 | <ol style="list-style-type: none">1. Midwife role clarification.2. Addition of a list of adverse events not to be reported (provided that they are not serious)3. Updating the protocol and the information note in accordance with General Data Protection Regulation (GDPR)4. Update of the SPC of Exacyl (Annex 2 of the protocol)5. Update of the coordinating correspondents6. Various typo corrections |
| 31 May 2019 | <ol style="list-style-type: none">1. Increase in the number of expected patients2. Punctual corrections in the protocol3. Timing of study treatment4. Modification of principal investigator for 2 sites : CHU de Besançon and CHU de Strasbourg |

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/33913639>

<http://www.ncbi.nlm.nih.gov/pubmed/32005192>