



## Clinical trial results:

### A Multicenter, Long-term Follow-up Study of the Safety and Efficacy of BOTOX® (Botulinum Toxin Type A) Purified Neurotoxin Complex in Patients with Urinary Incontinence Due to Neurogenic Detrusor Overactivity

#### Summary

|                          |                                  |
|--------------------------|----------------------------------|
| EudraCT number           | 2009-009216-53                   |
| Trial protocol           | PT NL GB FR DE IT ES BE AT CZ SK |
| Global end of trial date | 04 September 2013                |

#### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 01 June 2016 |
| First version publication date | 01 June 2016 |

#### Trial information

##### Trial identification

|                       |            |
|-----------------------|------------|
| Sponsor protocol code | 191622-094 |
|-----------------------|------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT00876447 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Allergan Limited  |
| Sponsor organisation address | Allergan Limited Marlow International The Parkway, Marlow, United Kingdom, SL7 1YL                    |
| Public contact               | Allergan Limited EU Regulatory Dept, Allergan Limited, 44 1628 494444, ml-eu_reg_affairs@allergan.com |
| Scientific contact           | Allergan Limited EU Regulatory Dept, Allergan Limited, 44 1628 494444, ml-eu_reg_affairs@allergan.com |

Notes:

#### Paediatric regulatory details

|  |    |
|--|----|
| Is trial part of an agreed paediatric investigation plan (PIP)       | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

|  |                   |
|--|-------------------|
| Analysis stage                                       | Final             |
| Date of interim/final analysis                       | 14 March 2014     |
| Is this the analysis of the primary completion data? | Yes               |
| Primary completion date                              | 12 June 2013      |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 04 September 2013 |
| Was the trial ended prematurely?                     | No                |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the long-term safety and maintenance of efficacy of BOTOX injected into the detrusor for the treatment of urinary incontinence caused by neurogenic detrusor overactivity in patients not been adequately managed with anticholinergic therapy

Protection of trial subjects:

All study participants were required to read and sign an Informed Consent Form

Background therapy: -

Evidence for comparator: -

|   |               |
|---|---------------|
| Actual start date of recruitment                          | 04 April 2009 |
| Long term follow-up planned                               | No            |
| Independent data monitoring committee (IDMC) involvement? | No            |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |                         |
|--------------------------------------|-------------------------|
| Country: Number of subjects enrolled | United States: 209      |
| Country: Number of subjects enrolled | United Kingdom: 15      |
| Country: Number of subjects enrolled | Australia: 16           |
| Country: Number of subjects enrolled | Austria: 2              |
| Country: Number of subjects enrolled | Belgium: 16             |
| Country: Number of subjects enrolled | Brazil: 15              |
| Country: Number of subjects enrolled | Canada: 20              |
| Country: Number of subjects enrolled | Czech Republic: 15      |
| Country: Number of subjects enrolled | Spain: 2                |
| Country: Number of subjects enrolled | France: 7               |
| Country: Number of subjects enrolled | Germany: 5              |
| Country: Number of subjects enrolled | Italy: 1                |
| Country: Number of subjects enrolled | Netherlands Antilles: 9 |
| Country: Number of subjects enrolled | New Zealand: 1          |
| Country: Number of subjects enrolled | Poland: 9               |
| Country: Number of subjects enrolled | Portugal: 12            |
| Country: Number of subjects enrolled | Taiwan: 3               |
| Country: Number of subjects enrolled | South Africa: 3         |
| Country: Number of subjects enrolled | Singapore: 2            |
| Country: Number of subjects enrolled | Slovakia: 6             |
| Country: Number of subjects enrolled | Russian Federation: 8   |

|                                      |             |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Ukraine: 12 |
| Worldwide total number of subjects   | 388         |
| EEA total number of subjects         | 90          |

Notes:

| <b>Subjects enrolled per age group</b>    |     |
|---|-----|
| 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)                      | 363 |
| From 65 to 84 years                       | 25  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

This was a long-term follow-up study that enrolled patients after participation in Study 191622-515 or 191622-516. A total of 397 patients were enrolled and 388 patients received at least 1 BOTOX treatment in study 191622-094 or in the preceding studies.

### Pre-assignment

Screening details:

The protocol was amended to remove the 300 U dose. Patients ongoing in the study who were treated with 300 U BOTOX prior to the amendment were assigned to 200 U BOTOX for all subsequent treatments. Participant Flow and Baseline Characteristics are based on the first BOTOX dose that patients received.

### Period 1

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

### Arms

|                              |                             |
|------------------------------|-----------------------------|
| Are arms mutually exclusive? | Yes                         |
| <b>Arm title</b>             | Botulinum Toxin Type A 300U |

Arm description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | Botulinum Toxin Type A |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Injection              |
| Routes of administration               | Intramuscular use      |

Dosage and administration details:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                  |                             |
|------------------|-----------------------------|
| <b>Arm title</b> | Botulinum Toxin Type A 200U |
|------------------|-----------------------------|

Arm description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|  |                        |
|--|------------------------|
| Arm type                               | Experimental           |
| Investigational medicinal product name | Botulinum Toxin Type A |
| Investigational medicinal product code |                        |
| Other name                             |                        |
| Pharmaceutical forms                   | Injection              |
| Routes of administration               | Intramuscular use      |

Dosage and administration details:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years.

| <b>Number of subjects in period 1</b> | <b>Botulinum Toxin<br/>Type A 300U</b> | <b>Botulinum Toxin<br/>Type A 200U</b> |
|---------------------------------------|--|--|
| Started                               | 185                                    | 203                                    |
| Completed                             | 105                                    | 122                                    |
| Not completed                         | 80                                     | 81                                     |
| Personal reasons                      | 30                                     | 28                                     |
| Adverse event, non-fatal              | 4                                      | 8                                      |
| Pregnancy                             | 4                                      | 2                                      |
| Other miscellaneous reasons           | 3                                      | 8                                      |
| Lost to follow-up                     | 6                                      | 15                                     |
| Site closure                          | 19                                     | 14                                     |
| Protocol deviation                    | 9                                      | 3                                      |
| Lack of efficacy                      | 5                                      | 3                                      |

## Baseline characteristics

### Reporting groups

|  |                             |
|--|-----------------------------|
| Reporting group title  | Botulinum Toxin Type A 300U |
| Reporting group description:<br>Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years. |                             |
| Reporting group title  | Botulinum Toxin Type A 200U |
| Reporting group description:<br>Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years. |                             |

| Reporting group values                     | Botulinum Toxin<br>Type A 300U | Botulinum Toxin<br>Type A 200U | Total |
|--|--------------------------------|--------------------------------|-------|
| Number of subjects                         | 185                            | 203                            | 388   |
| Age categorical<br>Units: Subjects         |                                |                                |       |
| Adults (18-64 years)                       | 171                            | 192                            | 363   |
| From 65-84 years                           | 14                             | 11                             | 25    |
| Age continuous<br>Units: years             |                                |                                |       |
| arithmetic mean                            | 46.3                           | 46.5                           |       |
| standard deviation                         | ± 12.96                        | ± 12.33                        | -     |
| Gender, Male/Female<br>Units: Participants |                                |                                |       |
| Female                                     | 116                            | 118                            | 234   |
| Male                                       | 69                             | 85                             | 154   |

## End points

### End points reporting groups

|  |                             |
|--|-----------------------------|
| Reporting group title  | Botulinum Toxin Type A 300U |
| Reporting group description:<br>Botulinum toxin Type A 300U injections into the detrusor > 12 weeks as needed for up to 3 years. |                             |
| Reporting group title  | Botulinum Toxin Type A 200U |
| Reporting group description:<br>Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years. |                             |

### Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

|  |  |
|--|--|
| End point title  | Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes <sup>[1]</sup> |
| End point description:<br>Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement). |  |
| End point type   | Primary  |
| End point timeframe:<br>Study Baseline, Week 6 Treatment Cycle 1   |  |

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No Statistical Analysis is reported for this outcome measure

| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 183                         | 201                         |  |  |
| Units: Incontinence Episodes                      |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline (BL)                               | 4.4 (± 2.54)                | 4.5 (± 2.64)                |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle1 (N=176, 195) | -3.4 (± 3.16)               | -3.2 (± 2.69)               |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

|                 |  |
|-----------------|--|
| End point title | Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes <sup>[2]</sup> |
|-----------------|--|

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**End point description:**

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

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**End point timeframe:**

Study Baseline, Week 6 Treatment Cycle 2

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**Notes:**

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No Statistical Analysis is reported for this outcome measure

| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 161                         | 186                         |  |  |
| Units: Incontinence Episodes                      |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline                                    | 4.5 (± 2.62)                | 4.6 (± 2.71)                |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle2 (N=153, 175) | -3.5 (± 3.13)               | -3.3 (± 2.85)               |  |  |

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**Statistical analyses**

No statistical analyses for this end point

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**Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes**

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|                 |  |
|-----------------|--|
| End point title | Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes <sup>[3]</sup> |
|-----------------|--|

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**End point description:**

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

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|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

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**End point timeframe:**

Study Baseline, Week 6 Treatment Cycle 3

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**Notes:**

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No Statistical Analysis is reported for this outcome measure



| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 118                         | 173                         |  |  |
| Units: Incontinence Episodes                      |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline                                    | 4.4 (± 2.33)                | 4.6 (± 2.65)                |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle3 (N=109, 164) | -3.3 (± 2.39)               | -3.5 (± 2.96)               |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

|                 |  |
|-----------------|--|
| End point title | Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes <sup>[4]</sup> |
|-----------------|--|

End point description:

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 4

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No Statistical Analysis is reported for this outcome measure

| End point values                                 | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|--|-----------------------------|-----------------------------|--|--|
| Subject group type                               | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                      | 67                          | 149                         |  |  |
| Units: Incontinence Episodes                     |                             |                             |  |  |
| arithmetic mean (standard deviation)             |                             |                             |  |  |
| Study Baseline                                   | 4.4 (± 2.13)                | 4.4 (± 2.57)                |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle4 (N=62, 141) | -3.4 (± 2.57)               | -3.5 (± 2.61)               |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes

|                 |  |
|-----------------|--|
| End point title | Change from Study Baseline in the Daily Average Number of Urinary Incontinence Episodes <sup>[5]</sup> |
|-----------------|--|

End point description:

Urinary incontinence is defined as involuntary loss of urine as recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-094 (or 7 days prior to each visit in study 191622-515 or 191622-516). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 7 consecutive days prior to the first treatment in either study 191622-515 or 191622-516. A negative number change from baseline indicates a reduction in incontinence episodes (improvement).

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 5

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No Statistical Analysis is reported for this outcome measure

| End point values                                | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                              | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                     | 33                          | 108                         |  |  |
| Units: Incontinence Episodes                    |                             |                             |  |  |
| arithmetic mean (standard deviation)            |                             |                             |  |  |
| Study Baseline                                  | 4.1 (± 2.34)                | 4.6 (± 2.57)                |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle5 (N=29, 99) | -3.7 (± 2.82)               | -3.6 (± 2.27)               |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

|                 |   |
|-----------------|---|
| End point title | Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score |
|-----------------|---|

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

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

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 1

| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 185                         | 202                         |  |  |
| Units: Scores on a Scale                          |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline                                    | 33.9 (± 18.19)              | 34.4 (± 18.18)              |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle1 (N=180, 199) | 32.3 (± 26.07)              | 30.3 (± 26.37)              |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

|  |   |
|--|---|
| End point title  | Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score |
| End point description:   |   |
| <p>The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.</p> |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| Study Baseline, Week 6 Treatment Cycle 2   |   |

| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 162                         | 185                         |  |  |
| Units: Scores on a Scale                          |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline                                    | 33.3 (± 18.17)              | 33.8 (± 18.17)              |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle2 (N=157, 178) | 31.4 (± 27.73)              | 33.5 (± 26.23)              |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change from Study Baseline in the Incontinence Quality of Life

**Instrument (I-QOL) Total Summary Score**

|                 |   |
|-----------------|---|
| End point title | Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score |
|-----------------|---|

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

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

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 3

| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 118                         | 173                         |  |  |
| Units: Scores on a Scale                          |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline                                    | 32.5 (± 17.83)              | 34.8 (± 18.95)              |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle3 (N=114, 164) | 28.8 (± 28.96)              | 30.4 (± 29.25)              |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score**

|                 |   |
|-----------------|---|
| End point title | Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score |
|-----------------|---|

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

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

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 4

| End point values                                 | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|--|-----------------------------|-----------------------------|--|--|
| Subject group type                               | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                      | 66                          | 151                         |  |  |
| Units: Scores on a Scale                         |                             |                             |  |  |
| arithmetic mean (standard deviation)             |                             |                             |  |  |
| Study Baseline                                   | 27.9 (± 16.66)              | 35.5 (± 17.7)               |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle4 (N=63, 147) | 30.4 (± 31.77)              | 30.1 (± 26.07)              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score

|                 |   |
|-----------------|---|
| End point title | Change from Study Baseline in the Incontinence Quality of Life Instrument (I-QOL) Total Summary Score |
|-----------------|---|

End point description:

The I-QOL questionnaire is a validated, disease-specific quality of life (QOL) questionnaire containing 22 questions designed to measure the impact of urinary incontinence on patients' lives. Each question is answered on a 5-point scale (1 = worst QOL and 5 = best QOL). The scores are totaled over the 22 questions and normalized to a score of 0-100 (0 = worst QOL and 100= best QOL). The I-QOL total score is calculated by combining the 22-item subscores from the 3 I-QOL domains: Avoidance Limiting Behavior, Psychological Impact, and Social Embarrassment. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improved QOL.

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

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 5

| End point values                                 | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|--|-----------------------------|-----------------------------|--|--|
| Subject group type                               | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                      | 31                          | 109                         |  |  |
| Units: Scores on a Scale                         |                             |                             |  |  |
| arithmetic mean (standard deviation)             |                             |                             |  |  |
| Study Baseline                                   | 32 (± 16.13)                | 33 (± 19.61)                |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle5 (N=28, 100) | 36.6 (± 28.28)              | 27.1 (± 24.54)              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Study Baseline in Volume Per Void

|  |   |
|--|---|
| End point title  | Change from Study Baseline in Volume Per Void |
| End point description:<br>The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement. |   |
| End point type   | Secondary                                     |
| End point timeframe:<br>Study Baseline, Week 6 Treatment Cycle 1   |   |

| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 178                         | 196                         |  |  |
| Units: Milliliters (mL)                           |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline                                    | 147.3 (± 90.15)             | 154.2 (± 96.54)             |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle1 (N=168, 186) | 133.8 (± 137.23)            | 133.2 (± 128.19)            |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Study Baseline in Volume Per Void

|  |   |
|--|---|
| End point title  | Change from Study Baseline in Volume Per Void |
| End point description:<br>The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement. |   |
| End point type   | Secondary                                     |
| End point timeframe:<br>Study Baseline, Week 6 Treatment Cycle 2   |   |

| End point values                     | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|--------------------------------------|-----------------------------|-----------------------------|--|--|
| Subject group type                   | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed          | 157                         | 181                         |  |  |
| Units: Milliliters (mL)              |                             |                             |  |  |
| arithmetic mean (standard deviation) |                             |                             |  |  |

|   |                 |                  |  |  |
|---|-----------------|------------------|--|--|
| Study Baseline                                    | 149.8 (± 91.03) | 151.9 (± 95.22)  |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle2 (N=146, 168) | 148 (± 134.45)  | 135.1 (± 127.62) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Study Baseline in Volume Per Void

|                 |   |
|-----------------|---|
| End point title | Change from Study Baseline in Volume Per Void |
|-----------------|---|

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

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

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 3

| End point values                                  | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                                | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                       | 114                         | 168                         |  |  |
| Units: Milliliters (mL)                           |                             |                             |  |  |
| arithmetic mean (standard deviation)              |                             |                             |  |  |
| Study Baseline                                    | 155 (± 90.7)                | 149.6 (± 91.12)             |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle3 (N=105, 158) | 166.9 (± 133.59)            | 157.5 (± 129.81)            |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Study Baseline in Volume Per Void

|                 |   |
|-----------------|---|
| End point title | Change from Study Baseline in Volume Per Void |
|-----------------|---|

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

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

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 4

| End point values                                 | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|--|-----------------------------|-----------------------------|--|--|
| Subject group type                               | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                      | 65                          | 143                         |  |  |
| Units: Milliliters (mL)                          |                             |                             |  |  |
| arithmetic mean (standard deviation)             |                             |                             |  |  |
| Study Baseline                                   | 159.7 (± 89.37)             | 151.7 (± 93.65)             |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle4 (N=61, 135) | 170.8 (± 128.26)            | 147.3 (± 122.09)            |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change from Study Baseline in Volume Per Void

|                 |   |
|-----------------|---|
| End point title | Change from Study Baseline in Volume Per Void |
|-----------------|---|

End point description:

The total volume voided (voluntary or by catheterization) is recorded by the patient over a 24-hour period preceding the study visit. The average volume per voiding episode is derived by dividing the total volume collected in a 24-hour period by the total number of urinary episodes with volume recorded in the same 24-hour period. The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-515 or 191622-516. Positive number changes from baseline indicate improvement.

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

End point timeframe:

Study Baseline, Week 6 Treatment Cycle 5

| End point values                                | Botulinum Toxin Type A 300U | Botulinum Toxin Type A 200U |  |  |
|---|-----------------------------|-----------------------------|--|--|
| Subject group type                              | Reporting group             | Reporting group             |  |  |
| Number of subjects analysed                     | 32                          | 104                         |  |  |
| Units: Milliliters (mL)                         |                             |                             |  |  |
| arithmetic mean (standard deviation)            |                             |                             |  |  |
| Study Baseline                                  | 182.7 (± 85.03)             | 140.8 (± 91.32)             |  |  |
| Chg from Study BL at Wk 6 Tmt Cycle5 (N=28, 95) | 163.5 (± 106.44)            | 160.2 (± 119.4)             |  |  |



## Statistical analyses

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No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events were recorded from signing the informed consent to the end of study (Week 156).

Adverse event reporting additional description:

The Botox-Treated Population includes all patients who received at least 1 BOTOX treatment (in Study 191622-094, 191622-515 or 191622-516) and is used to assess adverse events (AEs) and serious adverse events (SAEs). AEs and SAEs are reported by treatment cycle.

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

### Dictionary used

|                 |        |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

|                    |      |
|--------------------|------|
| Dictionary version | 16.0 |
|--------------------|------|

### Reporting groups

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 300U Treatment Cycle 1 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 1 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 300U Treatment Cycle 2 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 2 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 300U Treatment Cycle 3 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 3 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 300U Treatment Cycle 4 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 4 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 300U Treatment Cycle 5 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 5 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 300U Treatment Cycle 6 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 6 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 300U Treatment Cycle 7 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 300U injections into the detrusor > 12 weeks for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 7 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 8 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |   |
|-----------------------|---|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 9 |
|-----------------------|---|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |  |
|-----------------------|--|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 10 |
|-----------------------|--|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |  |
|-----------------------|--|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 11 |
|-----------------------|--|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

|                       |  |
|-----------------------|--|
| Reporting group title | Botulinum Toxin Type A 200U Treatment Cycle 12 |
|-----------------------|--|

Reporting group description:

Botulinum toxin Type A 200U injections into the detrusor > 12 weeks as needed for up to 3 years.

| <b>Serious adverse events</b>                                       | Botulinum Toxin<br>Type A 300U<br>Treatment Cycle 1 | Botulinum Toxin<br>Type A 200U<br>Treatment Cycle 1 | Botulinum Toxin<br>Type A 300U<br>Treatment Cycle 2 |
|---|---|---|---|
| Total subjects affected by serious adverse events                   |   |   |   |
| subjects affected / exposed   | 28 / 185 (15.14%)                                   | 35 / 203 (17.24%)                                   | 26 / 163 (15.95%)                                   |
| number of deaths (all causes)                                       | 0   | 0   | 0   |
| number of deaths resulting from adverse events                      | 0   | 0   | 0   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |   |
| Basal Cell Carcinoma  |   |   |   |
| subjects affected / exposed   | 1 / 185 (0.54%)                                     | 0 / 203 (0.00%)                                     | 0 / 163 (0.00%)                                     |
| occurrences causally related to treatment / all                     | 0 / 1   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Prostate cancer   | Additional description: Males Only                  |   |   |
| subjects affected / exposed   | 1 / 185 (0.54%)                                     | 0 / 203 (0.00%)                                     | 0 / 163 (0.00%)                                     |
| occurrences causally related to treatment / all                     | 0 / 1   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Breast Cancer   |   |   |   |
| subjects affected / exposed   | 0 / 185 (0.00%)                                     | 2 / 203 (0.99%)                                     | 0 / 163 (0.00%)                                     |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 2   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |

|   |                                      |                 |                 |
|---|--------------------------------------|-----------------|-----------------|
| Squamous Cell Carcinoma                         |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Thyroid Neoplasm                                |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Squamous Cell Carcinoma of Skin                 |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Invasive Ductal Breast Carcinoma                |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Glioblastoma                                    |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Uterine Leiomyoma                               | Additional description: Females Only |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Vascular disorders                              |                                      |                 |                 |
| Hypertension                                    |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Peripheral Ischaemia                            |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Deep Vein Thrombosis                            |                                      |                 |                 |

|  |                                      |                 |                 |
|--|--------------------------------------|-----------------|-----------------|
| subjects affected / exposed                          | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Peripheral Vascular Disorder                         |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Surgical and medical procedures                      |                                      |                 |                 |
| Abortion Induced                                     | Additional description: Females Only |                 |                 |
| subjects affected / exposed                          | 0 / 185 (0.00%)                      | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| General disorders and administration site conditions |                                      |                 |                 |
| Adverse Drug Reaction                                |                                      |                 |                 |
| subjects affected / exposed                          | 1 / 185 (0.54%)                      | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Non-Cardiac Chest Pain                               |                                      |                 |                 |
| alternative assessment type: Non-systematic          |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 185 (0.00%)                      | 2 / 203 (0.99%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Pyrexia  |                                      |                 |                 |
| alternative assessment type: Non-systematic          |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 185 (0.00%)                      | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Device Dislocation                                   |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 185 (0.00%)                      | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Oedema Peripheral                                    |                                      |                 |                 |
| alternative assessment type: Non-systematic          |                                      |                 |                 |

|   |                                    |                 |                 |
|---|------------------------------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Device Deployment Issue                         |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Impaired Healing                                |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Device Malfunction                              |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Immune system disorders                         |                                    |                 |                 |
| Anaphylactic Reaction                           |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Reproductive system and breast disorders        |                                    |                 |                 |
| Epididymitis                                    | Additional description: Males Only |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Pelvic Prolapse                                 |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Erectile Dysfunction                            | Additional description: Males Only |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory, thoracic and mediastinal disorders |                 |                 |                 |
| Asthma  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory Failure                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia Aspiration                            |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumothorax                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pulmonary Embolism                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Psychiatric disorders                           |                 |                 |                 |
| Mental Status Changes                           |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Acute Psychosis                                 |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Depression                                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Confusional State                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Investigations                                  |                 |                 |                 |
| Urine Cytology Abnormal                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Medical observation                             |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Injury, poisoning and procedural complications  |                 |                 |                 |
| Craniocerebral Injury                           |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Tendon Rupture                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Concussion                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Fall  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Forearm Fracture                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Incisional Hernia                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Lower Limb Fracture                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Overdose  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Femur fracture                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hip Fracture                                    |                 |                 |                 |

|   |                                    |                 |                 |
|---|------------------------------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Tibia Fracture                                  |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Joint Dislocation                               |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Spinal Compression Fracture                     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Scar  |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Scrotal Haematoma                               | Additional description: Males Only |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Post Procedural Haemorrhage                     |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%)                    | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Foot Fracture                                   |                                    |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Ankle Fracture                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac disorders                               |                 |                 |                 |
| Myocardial Infarction                           |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Acute myocardial infarction                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Atrioventricular Block                          |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Angina Pectoris                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Atrial Fibrillation                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Arrhythmia                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Nervous system disorders                        |                 |                 |                 |
| Multiple Sclerosis Relapse                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 4 / 185 (2.16%) | 4 / 203 (1.97%) | 4 / 163 (2.45%) |
| occurrences causally related to treatment / all | 0 / 4           | 0 / 4           | 0 / 4           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Muscle Spasticity                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cerebrovascular Accident                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Ischaemic Stroke                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Myasthenia Gravis                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Multiple Sclerosis                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 2 / 163 (1.23%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Paraparesis                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Convulsion                                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Epilepsy  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cervical myelopathy                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Spinal Cord Compression                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Syncope   |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Blood and lymphatic system disorders            |                 |                 |                 |
| Neutropenia                                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Eye disorders                                   |                 |                 |                 |
| Vision Blurred                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal disorders                      |                 |                 |                 |
| Intestinal Obstruction                          |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 2 / 185 (1.08%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Enterocolitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Umbilical Hernia                                |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Enterocutaneous Fistula                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Faecaloma                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Abdominal pain                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Colitis Ischaemic                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Diarrhoea                                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| Haemorrhoidal Haemorrhage<br>alternative assessment type: Non-systematic |                 |                 |                 |
| subjects affected / exposed  | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all                          | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                               | 0 / 0           | 0 / 0           | 0 / 0           |
| Large Intestine Perforation  |                 |                 |                 |
| subjects affected / exposed  | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all                          | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                               | 0 / 0           | 0 / 0           | 0 / 0           |
| Lower Gastrointestinal Haemorrhage                                       |                 |                 |                 |
| subjects affected / exposed  | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all                          | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                               | 0 / 0           | 0 / 0           | 0 / 0           |
| Melaena  |                 |                 |                 |
| alternative assessment type: Non-systematic                              |                 |                 |                 |
| subjects affected / exposed  | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all                          | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                               | 0 / 0           | 0 / 0           | 0 / 0           |
| Small Intestinal Obstruction   |                 |                 |                 |
| subjects affected / exposed  | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all                          | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                               | 0 / 0           | 0 / 0           | 0 / 0           |
| Volvulus   |                 |                 |                 |
| subjects affected / exposed  | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all                          | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                               | 0 / 0           | 0 / 0           | 0 / 0           |
| Constipation   |                 |                 |                 |
| alternative assessment type: Non-systematic                              |                 |                 |                 |
| subjects affected / exposed  | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all                          | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                               | 0 / 0           | 0 / 0           | 0 / 0           |
| Hepatobiliary disorders  |                 |                 |                 |
| Cholecystitis Acute  |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cholecystitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Decubitus Ulcer                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 2 / 185 (1.08%) | 4 / 203 (1.97%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 4           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Renal and urinary disorders                     |                 |                 |                 |
| Urinary Retention                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urethral Haemorrhage                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Stress Urinary Incontinence                     |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bladder Neck Obstruction                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Haematuria                                      |                 |                 |                 |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urethral Stenosis                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Nephrolithiasis                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Neurogenic Bladder                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urinary Incontinence                            |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hydronephrosis                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hydroureter                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Endocrine disorders                             |                 |                 |                 |
| Hyperthyroidism                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Musculoskeletal and connective tissue disorders |                 |                 |                 |
| Lumbar Spinal Stenosis                          |                 |                 |                 |
| subjects affected / exposed                     | 2 / 185 (1.08%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Spondylolisthesis                               |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Foot Deformity                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Intervertebral Disc Protrusion                  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Muscular Weakness                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 2 / 203 (0.99%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Back Pain                                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Vertebral Foraminal Stenosis                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bone Pain                                       |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Lupus-Like Syndrome                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Costochondritis                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Exostosis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Osteoarthritis                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Arthralgia                                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cervical Spinal Stenosis                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Rotator Cuff Syndrome                           |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Mobility Decreased                              |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Infections and infestations                     |                 |                 |                 |
| Urinary Tract Infection                         |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 7 / 185 (3.78%) | 5 / 203 (2.46%) | 3 / 163 (1.84%) |
| occurrences causally related to treatment / all | 2 / 7           | 3 / 5           | 1 / 3           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Clostridium Difficile Colitis                   |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pyelonephritis                                  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Upper Respiratory Tract Infection               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urinary Tract Infection Bacterial               |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urosepsis                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Wound Infection                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 185 (0.54%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Appendicitis                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cellulitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Escherichia Sepsis                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Meningitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Necrotising Fasciitis                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Paronychia                                      |                 |                 |                 |

|   |                 |                 |                 |  |
|---|-----------------|-----------------|-----------------|--|
| alternative assessment type: Non-systematic     |                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Sepsis  |                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Osteomyelitis                                   |                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Pyelonephritis Acute                            |                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 1 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Systemic Candida                                |                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 1 / 163 (0.61%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Localised Infection                             |                 |                 |                 |  |
| alternative assessment type: Non-systematic     |                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Abscess of Salivary Gland                       |                 |                 |                 |  |
| alternative assessment type: Non-systematic     |                 |                 |                 |  |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |  |
| Skin Infection                                  |                 |                 |                 |  |
| alternative assessment type: Non-systematic     |                 |                 |                 |  |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Device Related Infection                        |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bacteraemia                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Erysipelas                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Parotitis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Viral Infection                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Post Procedural Infection                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Subcutaneous Abscess                            |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Metabolism and nutrition disorders              |                 |                 |                 |
| Obesity   |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dehydration                                     |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hyperkalaemia                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hypoglycaemia                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

| Serious adverse events  | Botulinum Toxin Type A 200U Treatment Cycle 2 | Botulinum Toxin Type A 300U Treatment Cycle 3 | Botulinum Toxin Type A 200U Treatment Cycle 3 |
|---|---|---|---|
| Total subjects affected by serious adverse events                   |   |   |   |
| subjects affected / exposed   | 21 / 187 (11.23%)                             | 20 / 119 (16.81%)                             | 19 / 175 (10.86%)                             |
| number of deaths (all causes)                                       | 0   | 0   | 0   |
| number of deaths resulting from adverse events                      | 0   | 0   | 0   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |   |
| Basal Cell Carcinoma  |   |   |   |
| subjects affected / exposed   | 1 / 187 (0.53%)                               | 0 / 119 (0.00%)                               | 0 / 175 (0.00%)                               |
| occurrences causally related to treatment / all                     | 0 / 1   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Prostate cancer   | Additional description: Males Only            |   |   |



|   |                                      |                 |                 |
|---|--------------------------------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Breast Cancer                                   |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Squamous Cell Carcinoma                         |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Thyroid Neoplasm                                |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Squamous Cell Carcinoma of Skin                 |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Invasive Ductal Breast Carcinoma                |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Glioblastoma                                    |                                      |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Uterine Leiomyoma                               | Additional description: Females Only |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| Vascular disorders                              |                                      |                 |                 |
| Hypertension                                    |                                      |                 |                 |

|  |                                      |                 |                 |
|--|--------------------------------------|-----------------|-----------------|
| subjects affected / exposed                          | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 2 / 175 (1.14%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 2           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Peripheral Ischaemia                                 |                                      |                 |                 |
| subjects affected / exposed                          | 1 / 187 (0.53%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Deep Vein Thrombosis                                 |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 187 (0.00%)                      | 1 / 119 (0.84%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Peripheral Vascular Disorder                         |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 187 (0.00%)                      | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Surgical and medical procedures                      |                                      |                 |                 |
| Abortion Induced                                     | Additional description: Females Only |                 |                 |
| subjects affected / exposed                          | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| General disorders and administration site conditions |                                      |                 |                 |
| Adverse Drug Reaction                                |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Non-Cardiac Chest Pain                               |                                      |                 |                 |
| alternative assessment type: Non-systematic          |                                      |                 |                 |
| subjects affected / exposed                          | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0           | 0 / 0           |
| Pyrexia  |                                      |                 |                 |
| alternative assessment type: Non-systematic          |                                      |                 |                 |

|   |                                    |                 |                 |
|---|------------------------------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Device Dislocation                              |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Oedema Peripheral                               |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Device Deployment Issue                         |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Impaired Healing                                |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Device Malfunction                              |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Immune system disorders                         |                                    |                 |                 |
| Anaphylactic Reaction                           |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Reproductive system and breast disorders        |                                    |                 |                 |
| Epididymitis                                    | Additional description: Males Only |                 |                 |

|   |                                    |                 |                 |
|---|------------------------------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Pelvic Prolapse                                 |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Erectile Dysfunction                            | Additional description: Males Only |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Respiratory, thoracic and mediastinal disorders |                                    |                 |                 |
| Asthma  |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Respiratory Failure                             |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Pneumonia Aspiration                            |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Pneumothorax                                    |                                    |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Pulmonary Embolism                              |                                    |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Psychiatric disorders                           |                 |                 |                 |
| Mental Status Changes                           |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Acute Psychosis                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Depression                                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Confusional State                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Investigations                                  |                 |                 |                 |
| Urine Cytology Abnormal                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Medical observation                             |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Injury, poisoning and procedural                |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| complications                                   |                 |                 |                 |
| Craniocerebral Injury                           |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Tendon Rupture                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Concussion                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Fall  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Forearm Fracture                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Incisional Hernia                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Lower Limb Fracture                             |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Overdose  |                 |                 |                 |

|   |                                    |                 |                 |
|---|------------------------------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Femur fracture                                  |                                    |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Hip Fracture                                    |                                    |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Tibia Fracture                                  |                                    |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Joint Dislocation                               |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Spinal Compression Fracture                     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Scar  |                                    |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%)                    | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0           |
| Scrotal Haematoma                               | Additional description: Males Only |                 |                 |
| alternative assessment type: Non-systematic     |                                    |                 |                 |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Post Procedural Haemorrhage<br>alternative assessment type: Non-systematic |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Foot Fracture  |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Ankle Fracture   |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Cardiac disorders  |                 |                 |                 |
| Myocardial Infarction  |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Acute myocardial infarction  |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Atrioventricular Block   |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Angina Pectoris  |                 |                 |                 |
| alternative assessment type: Non-systematic                                |                 |                 |                 |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Atrial Fibrillation                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Arrhythmia                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Nervous system disorders                        |                 |                 |                 |
| Multiple Sclerosis Relapse                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 3 / 119 (2.52%) | 3 / 175 (1.71%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 3           | 0 / 3           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Muscle Spasticity                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cerebrovascular Accident                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Ischaemic Stroke                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Myasthenia Gravis                               |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Multiple Sclerosis                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Paraparesis                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Convulsion                                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Epilepsy  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cervical myelopathy                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Spinal Cord Compression                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Syncope   |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Blood and lymphatic system disorders            |                 |                 |                 |
| Neutropenia                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Eye disorders                                   |                 |                 |                 |
| Vision Blurred                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrointestinal disorders                      |                 |                 |                 |
| Intestinal Obstruction                          |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Enterocolitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Umbilical Hernia                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Enterocutaneous Fistula                         |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Faecaloma                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Abdominal pain                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Colitis Ischaemic                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Diarrhoea                                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Haemorrhoidal Haemorrhage                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Large Intestine Perforation                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Lower Gastrointestinal Haemorrhage              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Melaena   |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Small Intestinal Obstruction                    |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Volvulus  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Constipation                                    |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hepatobiliary disorders                         |                 |                 |                 |
| Cholecystitis Acute                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cholecystitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Decubitus Ulcer                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 2 / 175 (1.14%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Renal and urinary disorders                     |                 |                 |                 |
| Urinary Retention                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urethral Haemorrhage                            |                 |                 |                 |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Stress Urinary Incontinence<br>alternative assessment type: Non-systematic |                 |                 |                 |
| subjects affected / exposed  | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Bladder Neck Obstruction   |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Haematuria   |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Urethral Stenosis  |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Nephrolithiasis  |                 |                 |                 |
| subjects affected / exposed  | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Neurogenic Bladder   |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |
| Urinary Incontinence<br>alternative assessment type: Non-systematic        |                 |                 |                 |
| subjects affected / exposed  | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all                                 | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Hydronephrosis                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hydroureter                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Endocrine disorders                             |                 |                 |                 |
| Hyperthyroidism                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Musculoskeletal and connective tissue disorders |                 |                 |                 |
| Lumbar Spinal Stenosis                          |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Spondylolisthesis                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Foot Deformity                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Intervertebral Disc Protrusion                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Muscular Weakness                               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Back Pain                                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Vertebral Foraminal Stenosis                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bone Pain                                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Lupus-Like Syndrome                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Costochondritis                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Exostosis                                       |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Osteoarthritis                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 187 (0.53%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Arthralgia                                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cervical Spinal Stenosis                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Rotator Cuff Syndrome                           |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Mobility Decreased                              |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Infections and infestations                     |                 |                 |                 |
| Urinary Tract Infection                         |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 3 / 119 (2.52%) | 2 / 175 (1.14%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 3           | 1 / 2           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Clostridium Difficile Colitis                   |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pyelonephritis                                  |                 |                 |                 |
| subjects affected / exposed                     | 3 / 187 (1.60%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Upper Respiratory Tract Infection               |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urinary Tract Infection Bacterial               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urosepsis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Wound Infection                                 |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Appendicitis                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Cellulitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Escherichia Sepsis                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Meningitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Necrotising Fasciitis                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 2 / 119 (1.68%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Paronychia                                      |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Sepsis  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 2 / 119 (1.68%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Osteomyelitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pyelonephritis Acute                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Systemic Candida                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Localised Infection                             |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 187 (0.53%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Abscess of Salivary Gland                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin Infection                                  |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 1 / 119 (0.84%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Device Related Infection                        |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Bacteraemia                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Erysipelas                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Parotitis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Viral Infection                                 |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Post Procedural Infection                       |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Subcutaneous Abscess                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Metabolism and nutrition disorders              |                 |                 |                 |
| Obesity   |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dehydration                                     |                 |                 |                 |
| alternative assessment type: Non-systematic     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hyperkalaemia                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hypoglycaemia                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

| Serious adverse events  | Botulinum Toxin<br>Type A 300U<br>Treatment Cycle 4 | Botulinum Toxin<br>Type A 200U<br>Treatment Cycle 4 | Botulinum Toxin<br>Type A 300U<br>Treatment Cycle 5 |
|---|---|---|---|
| Total subjects affected by serious adverse events                   |   |   |   |
| subjects affected / exposed   | 11 / 69 (15.94%)                                    | 20 / 153 (13.07%)                                   | 5 / 34 (14.71%)                                     |
| number of deaths (all causes)                                       | 0   | 0   | 0   |
| number of deaths resulting from adverse events                      | 0   | 0   | 0   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |   |
| Basal Cell Carcinoma  |   |   |   |
| subjects affected / exposed   | 0 / 69 (0.00%)                                      | 0 / 153 (0.00%)                                     | 2 / 34 (5.88%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 2   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Prostate cancer   | Additional description: Males Only                  |   |   |
| subjects affected / exposed   | 0 / 69 (0.00%)                                      | 0 / 153 (0.00%)                                     | 0 / 34 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Breast Cancer   |   |   |   |
| subjects affected / exposed   | 0 / 69 (0.00%)                                      | 0 / 153 (0.00%)                                     | 0 / 34 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Squamous Cell Carcinoma   |   |   |   |
| subjects affected / exposed   | 0 / 69 (0.00%)                                      | 0 / 153 (0.00%)                                     | 0 / 34 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Thyroid Neoplasm  |   |   |   |
| subjects affected / exposed   | 0 / 69 (0.00%)                                      | 0 / 153 (0.00%)                                     | 0 / 34 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Squamous Cell Carcinoma of Skin                                     |   |   |   |
| subjects affected / exposed   | 0 / 69 (0.00%)                                      | 1 / 153 (0.65%)                                     | 0 / 34 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 1   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Invasive Ductal Breast Carcinoma                                    |   |   |   |

|   |                                      |                 |                |
|---|--------------------------------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| Glioblastoma                                    |                                      |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| Uterine Leiomyoma                               | Additional description: Females Only |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| Vascular disorders                              |                                      |                 |                |
| Hypertension                                    |                                      |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| Peripheral Ischaemia                            |                                      |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| Deep Vein Thrombosis                            |                                      |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| Peripheral Vascular Disorder                    |                                      |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| Surgical and medical procedures                 |                                      |                 |                |
| Abortion Induced                                | Additional description: Females Only |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0           | 0 / 0          |
| General disorders and administration            |                                      |                 |                |

|   |                |                 |                |  |
|---|----------------|-----------------|----------------|--|
| site conditions                                 |                |                 |                |  |
| Adverse Drug Reaction                           |                |                 |                |  |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |  |
| Non-Cardiac Chest Pain                          |                |                 |                |  |
| alternative assessment type: Non-systematic     |                |                 |                |  |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |  |
| Pyrexia   |                |                 |                |  |
| alternative assessment type: Non-systematic     |                |                 |                |  |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |  |
| Device Dislocation                              |                |                 |                |  |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |  |
| Oedema Peripheral                               |                |                 |                |  |
| alternative assessment type: Non-systematic     |                |                 |                |  |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |  |
| Device Deployment Issue                         |                |                 |                |  |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |  |
| Impaired Healing                                |                |                 |                |  |
| alternative assessment type: Non-systematic     |                |                 |                |  |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |  |
| Device Malfunction                              |                |                 |                |  |



|   |                                    |                 |                |
|---|------------------------------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Immune system disorders                         |                                    |                 |                |
| Anaphylactic Reaction                           |                                    |                 |                |
| alternative assessment type: Non-systematic     |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Reproductive system and breast disorders        |                                    |                 |                |
| Epididymitis                                    | Additional description: Males Only |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Pelvic Prolapse                                 |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Erectile Dysfunction                            | Additional description: Males Only |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                                    |                 |                |
| Asthma  |                                    |                 |                |
| alternative assessment type: Non-systematic     |                                    |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Respiratory Failure                             |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Pneumonia Aspiration                            |                                    |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Pneumothorax                                    |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Pulmonary Embolism                              |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Psychiatric disorders                           |                |                 |                |
| Mental Status Changes                           |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Acute Psychosis                                 |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Depression                                      |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Confusional State                               |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Investigations                                  |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| Urine Cytology Abnormal                         |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Medical observation                             |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Injury, poisoning and procedural complications  |                |                 |                |
| Craniocerebral Injury                           |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Tendon Rupture                                  |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Concussion                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Fall  |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Forearm Fracture                                |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| Incisional Hernia                               |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Lower Limb Fracture                             |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Overdose  |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Femur fracture                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hip Fracture                                    |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Tibia Fracture                                  |                |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Joint Dislocation                               |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Spinal Compression Fracture                     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |

|   |                                    |                 |                |
|---|------------------------------------|-----------------|----------------|
| Scar  |                                    |                 |                |
| alternative assessment type: Non-systematic     |                                    |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Scrotal Haematoma                               | Additional description: Males Only |                 |                |
| alternative assessment type: Non-systematic     |                                    |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Post Procedural Haemorrhage                     |                                    |                 |                |
| alternative assessment type: Non-systematic     |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Foot Fracture                                   |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Ankle Fracture                                  |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Cardiac disorders                               |                                    |                 |                |
| Myocardial Infarction                           |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Acute myocardial infarction                     |                                    |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%)                     | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0           | 0 / 0          |
| Atrioventricular Block                          |                                    |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Angina Pectoris                                 |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Atrial Fibrillation                             |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Arrhythmia                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Nervous system disorders                        |                |                 |                |
| Multiple Sclerosis Relapse                      |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 4 / 69 (5.80%) | 2 / 153 (1.31%) | 1 / 34 (2.94%) |
| occurrences causally related to treatment / all | 0 / 4          | 0 / 2           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Muscle Spasticity                               |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Cerebrovascular Accident                        |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Ischaemic Stroke                                |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Myasthenia Gravis                               |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Multiple Sclerosis                              |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Paraparesis                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Convulsion                                      |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Epilepsy  |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Cervical myelopathy                             |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Spinal Cord Compression                         |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Syncope   |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Blood and lymphatic system disorders            |                |                 |                |
| Neutropenia                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Eye disorders                                   |                |                 |                |
| Vision Blurred                                  |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Gastrointestinal disorders                      |                |                 |                |
| Intestinal Obstruction                          |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Enterocolitis                                   |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Umbilical Hernia                                |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Enterocutaneous Fistula                         |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Faecaloma                                       |                |                 |                |



|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Abdominal pain                                  |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Colitis Ischaemic                               |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Diarrhoea                                       |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Haemorrhoidal Haemorrhage                       |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Large Intestine Perforation                     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Lower Gastrointestinal Haemorrhage              |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Melaena   |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Small Intestinal Obstruction                    |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Volvulus  |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Constipation                                    |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hepatobiliary disorders                         |                |                 |                |
| Cholecystitis Acute                             |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Cholecystitis                                   |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                |                 |                |
| Decubitus Ulcer                                 |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 1 / 34 (2.94%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Renal and urinary disorders                     |                |                 |                |
| Urinary Retention                               |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Urethral Haemorrhage                            |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Stress Urinary Incontinence                     |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Bladder Neck Obstruction                        |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Haematuria                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Urethral Stenosis                               |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Nephrolithiasis                                 |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Neurogenic Bladder                              |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Urinary Incontinence                            |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hydronephrosis                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hydroureter                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Endocrine disorders                             |                |                 |                |
| Hyperthyroidism                                 |                |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Musculoskeletal and connective tissue disorders |                |                 |                |
| Lumbar Spinal Stenosis                          |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Spondylolisthesis                               |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Foot Deformity                                  |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Intervertebral Disc Protrusion                  |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Muscular Weakness                               |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Back Pain                                       |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Vertebral Foraminal Stenosis                    |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Bone Pain                                       |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Lupus-Like Syndrome                             |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Costochondritis                                 |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Exostosis                                       |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Osteoarthritis                                  |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Arthralgia                                      |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Cervical Spinal Stenosis                        |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Rotator Cuff Syndrome                           |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Mobility Decreased                              |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Infections and infestations                     |                |                 |                |
| Urinary Tract Infection                         |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 1 / 34 (2.94%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| Pneumonia                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Clostridium Difficile Colitis                   |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Pyelonephritis                                  |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Upper Respiratory Tract Infection               |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Urinary Tract Infection Bacterial               |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Urosepsis                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Wound Infection                                 |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Appendicitis                                    |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Cellulitis                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Escherichia Sepsis                              |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Meningitis                                      |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Necrotising Fasciitis                           |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Paronychia                                      |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Sepsis  |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Osteomyelitis                                   |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Pyelonephritis Acute                            |                |                 |                |



|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 3 / 153 (1.96%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 3           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Systemic Candida                                |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Localised Infection                             |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Abscess of Salivary Gland                       |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Skin Infection                                  |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Device Related Infection                        |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 1 / 69 (1.45%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Bacteraemia                                     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Erysipelas                                      |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Parotitis                                       |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Viral Infection                                 |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Post Procedural Infection                       |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Subcutaneous Abscess                            |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Metabolism and nutrition disorders              |                |                 |                |
| Obesity   |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Dehydration                                     |                |                 |                |
| alternative assessment type: Non-systematic     |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hyperkalaemia                                   |                |                 |                |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |
| Hypoglycaemia                                   |                |                 |                |
| subjects affected / exposed                     | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0           | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0           | 0 / 0          |

| <b>Serious adverse events</b>                                       | Botulinum Toxin<br>Type A 200U<br>Treatment Cycle 5 | Botulinum Toxin<br>Type A 300U<br>Treatment Cycle 6 | Botulinum Toxin<br>Type A 200U<br>Treatment Cycle 6 |
|---|---|---|---|
| Total subjects affected by serious adverse events                   |   |   |   |
| subjects affected / exposed   | 11 / 110 (10.00%)                                   | 0 / 16 (0.00%)                                      | 9 / 70 (12.86%)                                     |
| number of deaths (all causes)                                       | 0   | 0   | 0   |
| number of deaths resulting from adverse events                      | 0   | 0   | 0   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |   |
| Basal Cell Carcinoma  |   |   |   |
| subjects affected / exposed   | 0 / 110 (0.00%)                                     | 0 / 16 (0.00%)                                      | 0 / 70 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Prostate cancer   | Additional description: Males Only                  |   |   |
| subjects affected / exposed   | 0 / 110 (0.00%)                                     | 0 / 16 (0.00%)                                      | 0 / 70 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Breast Cancer   |   |   |   |
| subjects affected / exposed   | 0 / 110 (0.00%)                                     | 0 / 16 (0.00%)                                      | 0 / 70 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Squamous Cell Carcinoma   |   |   |   |
| subjects affected / exposed   | 0 / 110 (0.00%)                                     | 0 / 16 (0.00%)                                      | 0 / 70 (0.00%)                                      |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Thyroid Neoplasm  |   |   |   |

|   |                                      |                |                |
|---|--------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Squamous Cell Carcinoma of Skin                 |                                      |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Invasive Ductal Breast Carcinoma                |                                      |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Glioblastoma                                    |                                      |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Uterine Leiomyoma                               | Additional description: Females Only |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Vascular disorders                              |                                      |                |                |
| Hypertension                                    |                                      |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Peripheral Ischaemia                            |                                      |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Deep Vein Thrombosis                            |                                      |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Peripheral Vascular Disorder                    |                                      |                |                |

|  |                                      |                |                |
|--|--------------------------------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Surgical and medical procedures                      |                                      |                |                |
| Abortion Induced                                     | Additional description: Females Only |                |                |
| subjects affected / exposed                          | 1 / 110 (0.91%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                                      |                |                |
| Adverse Drug Reaction                                |                                      |                |                |
| subjects affected / exposed                          | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Non-Cardiac Chest Pain                               |                                      |                |                |
| alternative assessment type: Non-systematic          |                                      |                |                |
| subjects affected / exposed                          | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Pyrexia  |                                      |                |                |
| alternative assessment type: Non-systematic          |                                      |                |                |
| subjects affected / exposed                          | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Device Dislocation                                   |                                      |                |                |
| subjects affected / exposed                          | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Oedema Peripheral                                    |                                      |                |                |
| alternative assessment type: Non-systematic          |                                      |                |                |
| subjects affected / exposed                          | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Device Deployment Issue                              |                                      |                |                |

|   |                                    |                |                |
|---|------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Impaired Healing                                |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Device Malfunction                              |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Immune system disorders                         |                                    |                |                |
| Anaphylactic Reaction                           |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Reproductive system and breast disorders        |                                    |                |                |
| Epididymitis                                    | Additional description: Males Only |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Pelvic Prolapse                                 |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Erectile Dysfunction                            | Additional description: Males Only |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                                    |                |                |
| Asthma  |                                    |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Respiratory Failure                             |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pneumonia Aspiration                            |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pulmonary Embolism                              |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Psychiatric disorders                           |                 |                |                |
| Mental Status Changes                           |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Acute Psychosis                                 |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Depression                                      |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Confusional State                               |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Investigations                                  |                 |                |                |
| Urine Cytology Abnormal                         |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Medical observation                             |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural complications  |                 |                |                |
| Craniocerebral Injury                           |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Tendon Rupture                                  |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Concussion                                      |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |



|   |                 |                |                |
|---|-----------------|----------------|----------------|
| Fall  |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Forearm Fracture                                |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Incisional Hernia                               |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Lower Limb Fracture                             |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Overdose  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Femur fracture                                  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Hip Fracture                                    |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Tibia Fracture                                  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |

|   |                                    |                |                |
|---|------------------------------------|----------------|----------------|
| Joint Dislocation                               |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Spinal Compression Fracture                     |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Scar  |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Scrotal Haematoma                               | Additional description: Males Only |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Post Procedural Haemorrhage                     |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Foot Fracture                                   |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Ankle Fracture                                  |                                    |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%)                    | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Cardiac disorders                               |                                    |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| Myocardial Infarction                           |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Acute myocardial infarction                     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Atrioventricular Block                          |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Angina Pectoris                                 |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Atrial Fibrillation                             |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Arrhythmia                                      |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |                 |                |                |
| Multiple Sclerosis Relapse                      |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 3 / 70 (4.29%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 3          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Muscle Spasticity                               |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Cerebrovascular Accident                        |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Ischaemic Stroke                                |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Myasthenia Gravis                               |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Multiple Sclerosis                              |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Paraparesis                                     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Convulsion                                      |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Epilepsy  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Cervical myelopathy                             |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Spinal Cord Compression                         |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Syncope   |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Blood and lymphatic system disorders            |                 |                |                |
| Neutropenia                                     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Eye disorders                                   |                 |                |                |
| Vision Blurred                                  |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |                 |                |                |
| Intestinal Obstruction                          |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Enterocolitis                                   |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Umbilical Hernia                                |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Enterocutaneous Fistula                         |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Faecaloma                                       |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Abdominal pain                                  |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Colitis Ischaemic                               |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Diarrhoea                                       |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Haemorrhoidal Haemorrhage                       |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Large Intestine Perforation                     |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Lower Gastrointestinal Haemorrhage              |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Melaena   |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Small Intestinal Obstruction                    |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Volvulus  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Constipation                                    |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |                 |                |                |
| Cholecystitis Acute                             |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Cholecystitis                                   |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |                 |                |                |
| Decubitus Ulcer                                 |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |                 |                |                |
| Urinary Retention                               |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Urethral Haemorrhage                            |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Stress Urinary Incontinence                     |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Bladder Neck Obstruction                        |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Haematuria                                      |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Urethral Stenosis                               |                 |                |                |



|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Nephrolithiasis                                 |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Neurogenic Bladder                              |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Urinary Incontinence                            |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Hydronephrosis                                  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Hydroureter                                     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Endocrine disorders                             |                 |                |                |
| Hyperthyroidism                                 |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |                 |                |                |
| Lumbar Spinal Stenosis                          |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Spondylolisthesis                               |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Foot Deformity                                  |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Intervertebral Disc Protrusion                  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Muscular Weakness                               |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Back Pain                                       |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Vertebral Foraminal Stenosis                    |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Bone Pain                                       |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Lupus-Like Syndrome                             |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Costochondritis                                 |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Exostosis                                       |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Osteoarthritis                                  |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Arthralgia                                      |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Cervical Spinal Stenosis                        |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Rotator Cuff Syndrome                           |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Mobility Decreased                              |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Infections and infestations                     |                 |                |                |
| Urinary Tract Infection                         |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pneumonia                                       |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Clostridium Difficile Colitis                   |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Pyelonephritis                                  |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Upper Respiratory Tract Infection               |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Urinary Tract Infection Bacterial               |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Urosepsis                                       |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 1          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Wound Infection                                 |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Appendicitis                                    |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Cellulitis                                      |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Escherichia Sepsis                              |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Meningitis                                      |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Necrotising Fasciitis                           |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Paronychia                                      |                 |                |                |

|   |                 |                |                |  |
|---|-----------------|----------------|----------------|--|
| alternative assessment type: Non-systematic     |                 |                |                |  |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |  |
| Sepsis  |                 |                |                |  |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |  |
| Osteomyelitis                                   |                 |                |                |  |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |  |
| Pyelonephritis Acute                            |                 |                |                |  |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |  |
| Systemic Candida                                |                 |                |                |  |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |  |
| Localised Infection                             |                 |                |                |  |
| alternative assessment type: Non-systematic     |                 |                |                |  |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |  |
| Abscess of Salivary Gland                       |                 |                |                |  |
| alternative assessment type: Non-systematic     |                 |                |                |  |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |  |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |  |
| Skin Infection                                  |                 |                |                |  |
| alternative assessment type: Non-systematic     |                 |                |                |  |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Device Related Infection                        |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Bacteraemia                                     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Erysipelas                                      |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Parotitis                                       |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Viral Infection                                 |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Post Procedural Infection                       |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 1 / 110 (0.91%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Subcutaneous Abscess                            |                 |                |                |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |                 |                |                |
| Obesity   |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Dehydration                                     |                 |                |                |
| alternative assessment type: Non-systematic     |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Hyperkalaemia                                   |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |
| Hypoglycaemia                                   |                 |                |                |
| subjects affected / exposed                     | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0          | 0 / 0          |

| Serious adverse events  | Botulinum Toxin Type A 300U Treatment Cycle 7 | Botulinum Toxin Type A 200U Treatment Cycle 7 | Botulinum Toxin Type A 200U Treatment Cycle 8 |
|---|---|---|---|
| Total subjects affected by serious adverse events                   |   |   |   |
| subjects affected / exposed   | 0 / 8 (0.00%)                                 | 6 / 48 (12.50%)                               | 0 / 36 (0.00%)                                |
| number of deaths (all causes)                                       | 0   | 0   | 0   |
| number of deaths resulting from adverse events                      | 0   | 0   | 0   |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |   |   |
| Basal Cell Carcinoma  |   |   |   |
| subjects affected / exposed   | 0 / 8 (0.00%)                                 | 0 / 48 (0.00%)                                | 0 / 36 (0.00%)                                |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0   | 0 / 0   |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0   | 0 / 0   |
| Prostate cancer   | Additional description: Males Only            |   |   |



|   |                                      |                |                |
|---|--------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Breast Cancer                                   |                                      |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Squamous Cell Carcinoma                         |                                      |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Thyroid Neoplasm                                |                                      |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Squamous Cell Carcinoma of Skin                 |                                      |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Invasive Ductal Breast Carcinoma                |                                      |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Glioblastoma                                    |                                      |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Uterine Leiomyoma                               | Additional description: Females Only |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 1 / 48 (2.08%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| Vascular disorders                              |                                      |                |                |
| Hypertension                                    |                                      |                |                |

|  |                                      |                |                |
|--|--------------------------------------|----------------|----------------|
| subjects affected / exposed                          | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Peripheral Ischaemia                                 |                                      |                |                |
| subjects affected / exposed                          | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Deep Vein Thrombosis                                 |                                      |                |                |
| subjects affected / exposed                          | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Peripheral Vascular Disorder                         |                                      |                |                |
| subjects affected / exposed                          | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Surgical and medical procedures                      |                                      |                |                |
| Abortion Induced                                     | Additional description: Females Only |                |                |
| subjects affected / exposed                          | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| General disorders and administration site conditions |                                      |                |                |
| Adverse Drug Reaction                                |                                      |                |                |
| subjects affected / exposed                          | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Non-Cardiac Chest Pain                               |                                      |                |                |
| alternative assessment type: Non-systematic          |                                      |                |                |
| subjects affected / exposed                          | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all           | 0 / 0                                | 0 / 0          | 0 / 0          |
| Pyrexia  |                                      |                |                |
| alternative assessment type: Non-systematic          |                                      |                |                |

|   |                                    |                |                |
|---|------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Device Dislocation                              |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Oedema Peripheral                               |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Device Deployment Issue                         |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Impaired Healing                                |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Device Malfunction                              |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Immune system disorders                         |                                    |                |                |
| Anaphylactic Reaction                           |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Reproductive system and breast disorders        |                                    |                |                |
| Epididymitis                                    | Additional description: Males Only |                |                |

|   |                                    |                |                |
|---|------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Pelvic Prolapse                                 |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Erectile Dysfunction                            | Additional description: Males Only |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Respiratory, thoracic and mediastinal disorders |                                    |                |                |
| Asthma  |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Respiratory Failure                             |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Pneumonia Aspiration                            |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Pneumothorax                                    |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Pulmonary Embolism                              |                                    |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Psychiatric disorders                           |               |                |                |
| Mental Status Changes                           |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Acute Psychosis                                 |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Depression                                      |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Confusional State                               |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Investigations                                  |               |                |                |
| Urine Cytology Abnormal                         |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Medical observation                             |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Injury, poisoning and procedural                |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| complications                                   |               |                |                |
| Craniocerebral Injury                           |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Tendon Rupture                                  |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Concussion                                      |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Fall  |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Forearm Fracture                                |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Incisional Hernia                               |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lower Limb Fracture                             |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Overdose  |               |                |                |

|   |                                    |                |                |
|---|------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Femur fracture                                  |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Hip Fracture                                    |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Tibia Fracture                                  |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Joint Dislocation                               |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Spinal Compression Fracture                     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Scar  |                                    |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%)                      | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0          |
| Scrotal Haematoma                               | Additional description: Males Only |                |                |
| alternative assessment type: Non-systematic     |                                    |                |                |

|  |               |                |                |
|--|---------------|----------------|----------------|
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Post Procedural Haemorrhage<br>alternative assessment type: Non-systematic |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Foot Fracture  |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 1 / 48 (2.08%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Ankle Fracture   |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Cardiac disorders  |               |                |                |
| Myocardial Infarction  |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Acute myocardial infarction  |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Atrioventricular Block   |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Angina Pectoris<br>alternative assessment type: Non-systematic             |               |                |                |



|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Atrial Fibrillation                             |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Arrhythmia                                      |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Nervous system disorders                        |               |                |                |
| Multiple Sclerosis Relapse                      |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 2 / 48 (4.17%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 2          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Muscle Spasticity                               |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cerebrovascular Accident                        |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Ischaemic Stroke                                |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Myasthenia Gravis                               |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Multiple Sclerosis                              |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Paraparesis                                     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Convulsion                                      |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Epilepsy  |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cervical myelopathy                             |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Spinal Cord Compression                         |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Syncope   |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 1 / 48 (2.08%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|   |               |                |                |
|---|---------------|----------------|----------------|
| Blood and lymphatic system disorders            |               |                |                |
| Neutropenia                                     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Eye disorders                                   |               |                |                |
| Vision Blurred                                  |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Gastrointestinal disorders                      |               |                |                |
| Intestinal Obstruction                          |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Enterocolitis                                   |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Umbilical Hernia                                |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Enterocutaneous Fistula                         |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Faecaloma                                       |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Abdominal pain                                  |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Colitis Ischaemic                               |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Diarrhoea                                       |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Haemorrhoidal Haemorrhage                       |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Large Intestine Perforation                     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lower Gastrointestinal Haemorrhage              |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Melaena   |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Small Intestinal Obstruction                    |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Volvulus  |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Constipation                                    |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hepatobiliary disorders                         |               |                |                |
| Cholecystitis Acute                             |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cholecystitis                                   |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Skin and subcutaneous tissue disorders          |               |                |                |
| Decubitus Ulcer                                 |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 1 / 48 (2.08%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Renal and urinary disorders                     |               |                |                |
| Urinary Retention                               |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urethral Haemorrhage                            |               |                |                |

|  |               |                |                |
|--|---------------|----------------|----------------|
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Stress Urinary Incontinence<br>alternative assessment type: Non-systematic |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Bladder Neck Obstruction   |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Haematuria   |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Urethral Stenosis  |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Nephrolithiasis  |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Neurogenic Bladder   |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary Incontinence<br>alternative assessment type: Non-systematic        |               |                |                |
| subjects affected / exposed  | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all                            | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all                                 | 0 / 0         | 0 / 0          | 0 / 0          |

|   |               |                |                |
|---|---------------|----------------|----------------|
| Hydronephrosis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hydroureter                                     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Endocrine disorders                             |               |                |                |
| Hyperthyroidism                                 |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Musculoskeletal and connective tissue disorders |               |                |                |
| Lumbar Spinal Stenosis                          |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Spondylolisthesis                               |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Foot Deformity                                  |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Intervertebral Disc Protrusion                  |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Muscular Weakness                               |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Back Pain                                       |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Vertebral Foraminal Stenosis                    |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Bone Pain                                       |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Lupus-Like Syndrome                             |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Costochondritis                                 |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Exostosis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Osteoarthritis                                  |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |



|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Arthralgia                                      |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cervical Spinal Stenosis                        |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Rotator Cuff Syndrome                           |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Mobility Decreased                              |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 1 / 48 (2.08%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 1          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Infections and infestations                     |               |                |                |
| Urinary Tract Infection                         |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pneumonia                                       |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Clostridium Difficile Colitis                   |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis                                  |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Upper Respiratory Tract Infection               |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urinary Tract Infection Bacterial               |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Urosepsis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Wound Infection                                 |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Appendicitis                                    |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Cellulitis                                      |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|   |               |                |                |
|---|---------------|----------------|----------------|
| Escherichia Sepsis                              |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Meningitis                                      |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Necrotising Fasciitis                           |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Paronychia                                      |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Sepsis  |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Osteomyelitis                                   |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Pyelonephritis Acute                            |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Systemic Candida                                |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

|   |               |                |                |
|---|---------------|----------------|----------------|
| Localised Infection                             |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Abscess of Salivary Gland                       |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Skin Infection                                  |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Device Related Infection                        |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Bacteraemia                                     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Erysipelas                                      |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Parotitis                                       |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Viral Infection                                 |               |                |                |

|   |               |                |                |
|---|---------------|----------------|----------------|
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Post Procedural Infection                       |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Subcutaneous Abscess                            |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Metabolism and nutrition disorders              |               |                |                |
| Obesity   |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Dehydration                                     |               |                |                |
| alternative assessment type: Non-systematic     |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hyperkalaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |
| Hypoglycaemia                                   |               |                |                |
| subjects affected / exposed                     | 0 / 8 (0.00%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0         | 0 / 0          | 0 / 0          |
| deaths causally related to treatment / all      | 0 / 0         | 0 / 0          | 0 / 0          |

| Serious adverse events  | Botulinum Toxin<br>Type A 200U<br>Treatment Cycle 9 | Botulinum Toxin<br>Type A 200U<br>Treatment Cycle 10 | Botulinum Toxin<br>Type A 200U<br>Treatment Cycle 11 |
|---|---|--|--|
| Total subjects affected by serious adverse events                   |   |  |  |
| subjects affected / exposed   | 2 / 22 (9.09%)                                      | 1 / 11 (9.09%)                                       | 0 / 5 (0.00%)  |
| number of deaths (all causes)                                       | 0   | 0  | 0  |
| number of deaths resulting from adverse events                      | 0   | 0  | 0  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |   |  |  |
| Basal Cell Carcinoma  |   |  |  |
| subjects affected / exposed   | 0 / 22 (0.00%)                                      | 0 / 11 (0.00%)                                       | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |
| Prostate cancer   | Additional description: Males Only                  |  |  |
| subjects affected / exposed   | 0 / 22 (0.00%)                                      | 0 / 11 (0.00%)                                       | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |
| Breast Cancer   |   |  |  |
| subjects affected / exposed   | 0 / 22 (0.00%)                                      | 0 / 11 (0.00%)                                       | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |
| Squamous Cell Carcinoma   |   |  |  |
| subjects affected / exposed   | 0 / 22 (0.00%)                                      | 0 / 11 (0.00%)                                       | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |
| Thyroid Neoplasm  |   |  |  |
| subjects affected / exposed   | 0 / 22 (0.00%)                                      | 0 / 11 (0.00%)                                       | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |
| Squamous Cell Carcinoma of Skin                                     |   |  |  |
| subjects affected / exposed   | 0 / 22 (0.00%)                                      | 0 / 11 (0.00%)                                       | 0 / 5 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0   | 0 / 0  | 0 / 0  |
| deaths causally related to treatment / all                          | 0 / 0   | 0 / 0  | 0 / 0  |
| Invasive Ductal Breast Carcinoma                                    |   |  |  |

|   |                                      |                |               |
|---|--------------------------------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| Glioblastoma                                    |                                      |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| Uterine Leiomyoma                               | Additional description: Females Only |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| Vascular disorders                              |                                      |                |               |
| Hypertension                                    |                                      |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| Peripheral Ischaemia                            |                                      |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| Deep Vein Thrombosis                            |                                      |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| Peripheral Vascular Disorder                    |                                      |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| Surgical and medical procedures                 |                                      |                |               |
| Abortion Induced                                | Additional description: Females Only |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                                | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                                | 0 / 0          | 0 / 0         |
| General disorders and administration            |                                      |                |               |

|   |                |                |               |  |
|---|----------------|----------------|---------------|--|
| site conditions                                 |                |                |               |  |
| Adverse Drug Reaction                           |                |                |               |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |  |
| Non-Cardiac Chest Pain                          |                |                |               |  |
| alternative assessment type: Non-systematic     |                |                |               |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 1 / 11 (9.09%) | 0 / 5 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          | 0 / 0         |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |  |
| Pyrexia   |                |                |               |  |
| alternative assessment type: Non-systematic     |                |                |               |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |  |
| Device Dislocation                              |                |                |               |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |  |
| Oedema Peripheral                               |                |                |               |  |
| alternative assessment type: Non-systematic     |                |                |               |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |  |
| Device Deployment Issue                         |                |                |               |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |  |
| Impaired Healing                                |                |                |               |  |
| alternative assessment type: Non-systematic     |                |                |               |  |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |  |
| Device Malfunction                              |                |                |               |  |



|   |                                    |                |               |
|---|------------------------------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Immune system disorders                         |                                    |                |               |
| Anaphylactic Reaction                           |                                    |                |               |
| alternative assessment type: Non-systematic     |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Reproductive system and breast disorders        |                                    |                |               |
| Epididymitis                                    | Additional description: Males Only |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Pelvic Prolapse                                 |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Erectile Dysfunction                            | Additional description: Males Only |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Respiratory, thoracic and mediastinal disorders |                                    |                |               |
| Asthma  |                                    |                |               |
| alternative assessment type: Non-systematic     |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Respiratory Failure                             |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Pneumonia Aspiration                            |                                    |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Pneumothorax                                    |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Pulmonary Embolism                              |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Psychiatric disorders                           |                |                |               |
| Mental Status Changes                           |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Acute Psychosis                                 |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Depression                                      |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Confusional State                               |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Investigations                                  |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| Urine Cytology Abnormal                         |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Medical observation                             |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Injury, poisoning and procedural complications  |                |                |               |
| Craniocerebral Injury                           |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Tendon Rupture                                  |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Concussion                                      |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Fall  |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Forearm Fracture                                |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |

|   |                |                |               |
|---|----------------|----------------|---------------|
| Incisional Hernia                               |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Lower Limb Fracture                             |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Overdose  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Femur fracture                                  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Hip Fracture                                    |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Tibia Fracture                                  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Joint Dislocation                               |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Spinal Compression Fracture                     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |

|   |                                    |                |               |
|---|------------------------------------|----------------|---------------|
| Scar  |                                    |                |               |
| alternative assessment type: Non-systematic     |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Scrotal Haematoma                               | Additional description: Males Only |                |               |
| alternative assessment type: Non-systematic     |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Post Procedural Haemorrhage                     |                                    |                |               |
| alternative assessment type: Non-systematic     |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Foot Fracture                                   |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Ankle Fracture                                  |                                    |                |               |
| subjects affected / exposed                     | 1 / 22 (4.55%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Cardiac disorders                               |                                    |                |               |
| Myocardial Infarction                           |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Acute myocardial infarction                     |                                    |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%)                     | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0                              | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0                              | 0 / 0          | 0 / 0         |
| Atrioventricular Block                          |                                    |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Angina Pectoris                                 |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Atrial Fibrillation                             |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Arrhythmia                                      |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Nervous system disorders                        |                |                |               |
| Multiple Sclerosis Relapse                      |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Muscle Spasticity                               |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cerebrovascular Accident                        |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Ischaemic Stroke                                |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Myasthenia Gravis                               |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Multiple Sclerosis                              |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Paraparesis                                     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Convulsion                                      |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Epilepsy  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cervical myelopathy                             |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Spinal Cord Compression                         |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Syncope   |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Blood and lymphatic system disorders            |                |                |               |
| Neutropenia                                     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Eye disorders                                   |                |                |               |
| Vision Blurred                                  |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Gastrointestinal disorders                      |                |                |               |
| Intestinal Obstruction                          |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Enterocolitis                                   |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Umbilical Hernia                                |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Enterocutaneous Fistula                         |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Faecaloma                                       |                |                |               |



|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Abdominal pain                                  |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Colitis Ischaemic                               |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Diarrhoea                                       |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Haemorrhoidal Haemorrhage                       |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Large Intestine Perforation                     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Lower Gastrointestinal Haemorrhage              |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Melaena   |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Small Intestinal Obstruction                    |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Volvulus  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Constipation                                    |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Hepatobiliary disorders                         |                |                |               |
| Cholecystitis Acute                             |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cholecystitis                                   |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Skin and subcutaneous tissue disorders          |                |                |               |
| Decubitus Ulcer                                 |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Renal and urinary disorders                     |                |                |               |
| Urinary Retention                               |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Urethral Haemorrhage                            |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Stress Urinary Incontinence                     |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Bladder Neck Obstruction                        |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Haematuria                                      |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Urethral Stenosis                               |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Nephrolithiasis                                 |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Neurogenic Bladder                              |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Urinary Incontinence                            |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Hydronephrosis                                  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Hydroureter                                     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Endocrine disorders                             |                |                |               |
| Hyperthyroidism                                 |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Musculoskeletal and connective tissue disorders |                |                |               |
| Lumbar Spinal Stenosis                          |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Spondylolisthesis                               |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Foot Deformity                                  |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Intervertebral Disc Protrusion                  |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Muscular Weakness                               |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Back Pain                                       |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Vertebral Foraminal Stenosis                    |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Bone Pain                                       |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Lupus-Like Syndrome                             |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Costochondritis                                 |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Exostosis                                       |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Osteoarthritis                                  |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Arthralgia                                      |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cervical Spinal Stenosis                        |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Rotator Cuff Syndrome                           |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Mobility Decreased                              |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Infections and infestations                     |                |                |               |
| Urinary Tract Infection                         |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |

|   |                |                |               |
|---|----------------|----------------|---------------|
| Pneumonia                                       |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Clostridium Difficile Colitis                   |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Pyelonephritis                                  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Upper Respiratory Tract Infection               |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Urinary Tract Infection Bacterial               |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Urosepsis                                       |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Wound Infection                                 |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Appendicitis                                    |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Cellulitis                                      |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Escherichia Sepsis                              |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Meningitis                                      |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Necrotising Fasciitis                           |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Paronychia                                      |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Sepsis  |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Osteomyelitis                                   |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Pyelonephritis Acute                            |                |                |               |



|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Systemic Candida                                |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Localised Infection                             |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Abscess of Salivary Gland                       |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Skin Infection                                  |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Device Related Infection                        |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Bacteraemia                                     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Erysipelas                                      |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Parotitis                                       |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Viral Infection                                 |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Post Procedural Infection                       |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Subcutaneous Abscess                            |                |                |               |
| subjects affected / exposed                     | 1 / 22 (4.55%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Metabolism and nutrition disorders              |                |                |               |
| Obesity   |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Dehydration                                     |                |                |               |
| alternative assessment type: Non-systematic     |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Hyperkalaemia                                   |                |                |               |

|   |                |                |               |
|---|----------------|----------------|---------------|
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |
| Hypoglycaemia                                   |                |                |               |
| subjects affected / exposed                     | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 0          | 0 / 0         |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          | 0 / 0         |

| Serious adverse events  | Botulinum Toxin Type A 200U Treatment Cycle 12 |  |  |
|---|--|--|--|
| Total subjects affected by serious adverse events                   |  |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                                  |  |  |
| number of deaths (all causes)                                       | 0  |  |  |
| number of deaths resulting from adverse events                      | 0  |  |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |  |  |
| Basal Cell Carcinoma  |  |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                                  |  |  |
| occurrences causally related to treatment / all                     | 0 / 0  |  |  |
| deaths causally related to treatment / all                          | 0 / 0  |  |  |
| Prostate cancer   | Additional description: Males Only             |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                                  |  |  |
| occurrences causally related to treatment / all                     | 0 / 0  |  |  |
| deaths causally related to treatment / all                          | 0 / 0  |  |  |
| Breast Cancer   |  |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                                  |  |  |
| occurrences causally related to treatment / all                     | 0 / 0  |  |  |
| deaths causally related to treatment / all                          | 0 / 0  |  |  |
| Squamous Cell Carcinoma   |  |  |  |
| subjects affected / exposed   | 0 / 2 (0.00%)                                  |  |  |
| occurrences causally related to treatment / all                     | 0 / 0  |  |  |
| deaths causally related to treatment / all                          | 0 / 0  |  |  |
| Thyroid Neoplasm  |  |  |  |

|   |                                      |  |  |
|---|--------------------------------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Squamous Cell Carcinoma of Skin                 |                                      |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Invasive Ductal Breast Carcinoma                |                                      |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Glioblastoma                                    |                                      |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Uterine Leiomyoma                               | Additional description: Females Only |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Vascular disorders                              |                                      |  |  |
| Hypertension                                    |                                      |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Peripheral Ischaemia                            |                                      |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Deep Vein Thrombosis                            |                                      |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all | 0 / 0                                |  |  |
| deaths causally related to treatment / all      | 0 / 0                                |  |  |
| Peripheral Vascular Disorder                    |                                      |  |  |

|  |                                      |  |  |
|--|--------------------------------------|--|--|
| subjects affected / exposed                          | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                |  |  |
| deaths causally related to treatment / all           | 0 / 0                                |  |  |
| Surgical and medical procedures                      |                                      |  |  |
| Abortion Induced                                     | Additional description: Females Only |  |  |
| subjects affected / exposed                          | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                |  |  |
| deaths causally related to treatment / all           | 0 / 0                                |  |  |
| General disorders and administration site conditions |                                      |  |  |
| Adverse Drug Reaction                                |                                      |  |  |
| subjects affected / exposed                          | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                |  |  |
| deaths causally related to treatment / all           | 0 / 0                                |  |  |
| Non-Cardiac Chest Pain                               |                                      |  |  |
| alternative assessment type: Non-systematic          |                                      |  |  |
| subjects affected / exposed                          | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                |  |  |
| deaths causally related to treatment / all           | 0 / 0                                |  |  |
| Pyrexia  |                                      |  |  |
| alternative assessment type: Non-systematic          |                                      |  |  |
| subjects affected / exposed                          | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                |  |  |
| deaths causally related to treatment / all           | 0 / 0                                |  |  |
| Device Dislocation                                   |                                      |  |  |
| subjects affected / exposed                          | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                |  |  |
| deaths causally related to treatment / all           | 0 / 0                                |  |  |
| Oedema Peripheral                                    |                                      |  |  |
| alternative assessment type: Non-systematic          |                                      |  |  |
| subjects affected / exposed                          | 0 / 2 (0.00%)                        |  |  |
| occurrences causally related to treatment / all      | 0 / 0                                |  |  |
| deaths causally related to treatment / all           | 0 / 0                                |  |  |
| Device Deployment Issue                              |                                      |  |  |

|   |                                    |  |  |
|---|------------------------------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%)                      |  |  |
| occurrences causally related to treatment / all | 0 / 0                              |  |  |
| deaths causally related to treatment / all      | 0 / 0                              |  |  |
| Impaired Healing                                |                                    |  |  |
| alternative assessment type: Non-systematic     |                                    |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                      |  |  |
| occurrences causally related to treatment / all | 0 / 0                              |  |  |
| deaths causally related to treatment / all      | 0 / 0                              |  |  |
| Device Malfunction                              |                                    |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                      |  |  |
| occurrences causally related to treatment / all | 0 / 0                              |  |  |
| deaths causally related to treatment / all      | 0 / 0                              |  |  |
| Immune system disorders                         |                                    |  |  |
| Anaphylactic Reaction                           |                                    |  |  |
| alternative assessment type: Non-systematic     |                                    |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                      |  |  |
| occurrences causally related to treatment / all | 0 / 0                              |  |  |
| deaths causally related to treatment / all      | 0 / 0                              |  |  |
| Reproductive system and breast disorders        |                                    |  |  |
| Epididymitis                                    | Additional description: Males Only |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                      |  |  |
| occurrences causally related to treatment / all | 0 / 0                              |  |  |
| deaths causally related to treatment / all      | 0 / 0                              |  |  |
| Pelvic Prolapse                                 |                                    |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                      |  |  |
| occurrences causally related to treatment / all | 0 / 0                              |  |  |
| deaths causally related to treatment / all      | 0 / 0                              |  |  |
| Erectile Dysfunction                            | Additional description: Males Only |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%)                      |  |  |
| occurrences causally related to treatment / all | 0 / 0                              |  |  |
| deaths causally related to treatment / all      | 0 / 0                              |  |  |
| Respiratory, thoracic and mediastinal disorders |                                    |  |  |
| Asthma  |                                    |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Respiratory Failure                             |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Pneumonia Aspiration                            |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Pneumothorax                                    |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Pulmonary Embolism                              |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Psychiatric disorders                           |               |  |  |  |
| Mental Status Changes                           |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Acute Psychosis                                 |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Depression                                      |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |

|   |               |  |  |
|---|---------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Confusional State                               |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Investigations                                  |               |  |  |
| Urine Cytology Abnormal                         |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Medical observation                             |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Injury, poisoning and procedural complications  |               |  |  |
| Craniocerebral Injury                           |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Tendon Rupture                                  |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Concussion                                      |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |



|   |               |  |  |  |
|---|---------------|--|--|--|
| Fall  |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Forearm Fracture                                |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Incisional Hernia                               |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Lower Limb Fracture                             |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Overdose  |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Femur fracture                                  |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Hip Fracture                                    |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Tibia Fracture                                  |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |

|  |   |  |  |  |
|--|---|--|--|--|
| Joint Dislocation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all           | 0 / 2 (0.00%)<br>0 / 0<br>0 / 0                                       |  |  |  |
| Spinal Compression Fracture<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all  | 0 / 2 (0.00%)<br>0 / 0<br>0 / 0                                       |  |  |  |
| Scar<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all                        | 0 / 2 (0.00%)<br>0 / 0<br>0 / 0                                       |  |  |  |
| Scrotal Haematoma<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all           | Additional description: Males Only<br>0 / 2 (0.00%)<br>0 / 0<br>0 / 0 |  |  |  |
| Post Procedural Haemorrhage<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all | 0 / 2 (0.00%)<br>0 / 0<br>0 / 0                                       |  |  |  |
| Foot Fracture<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all  | 0 / 2 (0.00%)<br>0 / 0<br>0 / 0                                       |  |  |  |
| Ankle Fracture<br>subjects affected / exposed<br>occurrences causally related to treatment / all<br>deaths causally related to treatment / all   | 0 / 2 (0.00%)<br>0 / 0<br>0 / 0                                       |  |  |  |
| Cardiac disorders  |   |  |  |  |

|   |               |  |  |
|---|---------------|--|--|
| Myocardial Infarction                           |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Acute myocardial infarction                     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Atrioventricular Block                          |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Angina Pectoris                                 |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Atrial Fibrillation                             |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Arrhythmia                                      |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Nervous system disorders                        |               |  |  |
| Multiple Sclerosis Relapse                      |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Muscle Spasticity                               |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Cerebrovascular Accident                        |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Ischaemic Stroke                                |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Myasthenia Gravis                               |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Multiple Sclerosis                              |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Paraparesis                                     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Convulsion                                      |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Epilepsy  |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Cervical myelopathy                             |               |  |  |  |

|   |               |  |  |
|---|---------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Spinal Cord Compression                         |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Syncope   |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Blood and lymphatic system disorders            |               |  |  |
| Neutropenia                                     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Eye disorders                                   |               |  |  |
| Vision Blurred                                  |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Gastrointestinal disorders                      |               |  |  |
| Intestinal Obstruction                          |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Enterocolitis                                   |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Umbilical Hernia                                |               |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Enterocutaneous Fistula                         |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Faecaloma                                       |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Abdominal pain                                  |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Colitis Ischaemic                               |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Diarrhoea                                       |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Haemorrhoidal Haemorrhage                       |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Large Intestine Perforation                     |               |  |  |  |

|   |               |  |  |
|---|---------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Lower Gastrointestinal Haemorrhage              |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Melaena   |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Small Intestinal Obstruction                    |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Volvulus  |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Constipation                                    |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Hepatobiliary disorders                         |               |  |  |
| Cholecystitis Acute                             |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Cholecystitis                                   |               |  |  |

|   |               |  |  |
|---|---------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Skin and subcutaneous tissue disorders          |               |  |  |
| Decubitus Ulcer                                 |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Renal and urinary disorders                     |               |  |  |
| Urinary Retention                               |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Urethral Haemorrhage                            |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Stress Urinary Incontinence                     |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Bladder Neck Obstruction                        |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Haematuria                                      |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Urethral Stenosis                               |               |  |  |



|   |               |  |  |
|---|---------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Nephrolithiasis                                 |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Neurogenic Bladder                              |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Urinary Incontinence                            |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Hydronephrosis                                  |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Hydroureter                                     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Endocrine disorders                             |               |  |  |
| Hyperthyroidism                                 |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Musculoskeletal and connective tissue disorders |               |  |  |
| Lumbar Spinal Stenosis                          |               |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Spondylolisthesis                               |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Foot Deformity                                  |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Intervertebral Disc Protrusion                  |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Muscular Weakness                               |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Back Pain                                       |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Vertebral Foraminal Stenosis                    |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Bone Pain                                       |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Lupus-Like Syndrome                             |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Costochondritis                                 |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Exostosis                                       |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Osteoarthritis                                  |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Arthralgia                                      |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Cervical Spinal Stenosis                        |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Rotator Cuff Syndrome                           |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |

|   |               |  |  |
|---|---------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Mobility Decreased                              |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Infections and infestations                     |               |  |  |
| Urinary Tract Infection                         |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Pneumonia                                       |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Clostridium Difficile Colitis                   |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Pyelonephritis                                  |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Upper Respiratory Tract Infection               |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Urinary Tract Infection Bacterial               |               |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Urosepsis                                       |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Wound Infection                                 |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Appendicitis                                    |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Cellulitis                                      |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Escherichia Sepsis                              |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Meningitis                                      |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Necrotising Fasciitis                           |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Paronychia                                      |               |  |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Sepsis  |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Osteomyelitis                                   |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Pyelonephritis Acute                            |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Systemic Candida                                |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Localised Infection                             |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Abscess of Salivary Gland                       |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Skin Infection                                  |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |

|   |               |  |  |  |
|---|---------------|--|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Device Related Infection                        |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Bacteraemia                                     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Erysipelas                                      |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Parotitis                                       |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Viral Infection                                 |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Post Procedural Infection                       |               |  |  |  |
| alternative assessment type: Non-systematic     |               |  |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |  |
| Subcutaneous Abscess                            |               |  |  |  |

|   |               |  |  |
|---|---------------|--|--|
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Metabolism and nutrition disorders              |               |  |  |
| Obesity   |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Dehydration                                     |               |  |  |
| alternative assessment type: Non-systematic     |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Hyperkalaemia                                   |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |
| Hypoglycaemia                                   |               |  |  |
| subjects affected / exposed                     | 0 / 2 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0         |  |  |
| deaths causally related to treatment / all      | 0 / 0         |  |  |

Frequency threshold for reporting non-serious adverse events: 5 %

| Non-serious adverse events                            | Botulinum Toxin Type A 300U Treatment Cycle 1 | Botulinum Toxin Type A 200U Treatment Cycle 1 | Botulinum Toxin Type A 300U Treatment Cycle 2 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |
| subjects affected / exposed                           | 154 / 185 (83.24%)                            | 170 / 203 (83.74%)                            | 126 / 163 (77.30%)                            |
| General disorders and administration site conditions  |   |   |   |
| Oedema Peripheral                                     |   |   |   |
| alternative assessment type: Non-systematic           |   |   |   |
| subjects affected / exposed                           | 6 / 185 (3.24%)                               | 8 / 203 (3.94%)                               | 3 / 163 (1.84%)                               |
| occurrences (all)                                     | 6   | 10  | 5   |



|   |                                      |                                   |                                 |
|---|--------------------------------------|-----------------------------------|---------------------------------|
| <p>Fatigue</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>6 / 185 (3.24%)</p> <p>8</p>      | <p>13 / 203 (6.40%)</p> <p>14</p> | <p>4 / 163 (2.45%)</p> <p>4</p> |
| <p>Pyrexia</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>4 / 185 (2.16%)</p> <p>4</p>      | <p>17 / 203 (8.37%)</p> <p>19</p> | <p>5 / 163 (3.07%)</p> <p>6</p> |
| Reproductive system and breast disorders  |                                      |                                   |                                 |
| Ovarian Cyst  | Additional description: Females Only |                                   |                                 |
| subjects affected / exposed   | 0 / 185 (0.00%)                      | 0 / 203 (0.00%)                   | 0 / 163 (0.00%)                 |
| occurrences (all)   | 0                                    | 0                                 | 0                               |
| Vulvovaginal Pruritus   | Additional description: Females Only |                                   |                                 |
| alternative assessment type: Non-systematic   |                                      |                                   |                                 |
| subjects affected / exposed   | 0 / 185 (0.00%)                      | 1 / 203 (0.49%)                   | 0 / 163 (0.00%)                 |
| occurrences (all)   | 0                                    | 3                                 | 0                               |
| Respiratory, thoracic and mediastinal disorders   |                                      |                                   |                                 |
| Rhinitis Seasonal   |                                      |                                   |                                 |
| alternative assessment type: Non-systematic   |                                      |                                   |                                 |
| subjects affected / exposed   | 0 / 185 (0.00%)                      | 0 / 203 (0.00%)                   | 0 / 163 (0.00%)                 |
| occurrences (all)   | 0                                    | 0                                 | 0                               |
| Psychiatric disorders   |                                      |                                   |                                 |
| Depression  |                                      |                                   |                                 |
| alternative assessment type: Non-systematic   |                                      |                                   |                                 |
| subjects affected / exposed   | 5 / 185 (2.70%)                      | 6 / 203 (2.96%)                   | 3 / 163 (1.84%)                 |
| occurrences (all)   | 6                                    | 6                                 | 4                               |
| Investigations  |                                      |                                   |                                 |
| Expanded Disability Status Scale Score Increased  |                                      |                                   |                                 |
| subjects affected / exposed   | 7 / 185 (3.78%)                      | 10 / 203 (4.93%)                  | 13 / 163 (7.98%)                |
| occurrences (all)   | 9                                    | 10                                | 14                              |
| Haemoglobin Decreased   |                                      |                                   |                                 |
| subjects affected / exposed   | 0 / 185 (0.00%)                      | 0 / 203 (0.00%)                   | 0 / 163 (0.00%)                 |
| occurrences (all)   | 0                                    | 0                                 | 0                               |
| Central Nervous System Function Test Abnormal   |                                      |                                   |                                 |

|  |                      |                      |                      |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 185 (0.00%)<br>0 | 0 / 203 (0.00%)<br>0 | 0 / 163 (0.00%)<br>0 |
| Injury, poisoning and procedural complications   |                      |                      |                      |
| Fall   |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 5 / 185 (2.70%)      | 6 / 203 (2.96%)      | 7 / 163 (4.29%)      |
| occurrences (all)                                | 6                    | 13                   | 9                    |
| Muscle Strain                                    |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 0 / 185 (0.00%)      | 3 / 203 (1.48%)      | 1 / 163 (0.61%)      |
| occurrences (all)                                | 0                    | 3                    | 1                    |
| Hand Fracture                                    |                      |                      |                      |
| subjects affected / exposed                      | 0 / 185 (0.00%)      | 0 / 203 (0.00%)      | 0 / 163 (0.00%)      |
| occurrences (all)                                | 0                    | 0                    | 0                    |
| Contusion  |                      |                      |                      |
| subjects affected / exposed                      | 0 / 185 (0.00%)      | 2 / 203 (0.99%)      | 2 / 163 (1.23%)      |
| occurrences (all)                                | 0                    | 5                    | 3                    |
| Thermal Burn                                     |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 0 / 185 (0.00%)      | 2 / 203 (0.99%)      | 0 / 163 (0.00%)      |
| occurrences (all)                                | 0                    | 2                    | 0                    |
| Cardiac disorders                                |                      |                      |                      |
| Bundle Branch Block Right                        |                      |                      |                      |
| subjects affected / exposed                      | 0 / 185 (0.00%)      | 0 / 203 (0.00%)      | 0 / 163 (0.00%)      |
| occurrences (all)                                | 0                    | 0                    | 0                    |
| Nervous system disorders                         |                      |                      |                      |
| Muscle Spasticity                                |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 4 / 185 (2.16%)      | 1 / 203 (0.49%)      | 2 / 163 (1.23%)      |
| occurrences (all)                                | 5                    | 1                    | 2                    |
| Headache   |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 8 / 185 (4.32%)      | 9 / 203 (4.43%)      | 3 / 163 (1.84%)      |
| occurrences (all)                                | 8                    | 9                    | 3                    |
| Blood and lymphatic system disorders             |                      |                      |                      |

|  |                         |                         |                        |
|--|-------------------------|-------------------------|------------------------|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 185 (0.00%)<br>0    | 0 / 203 (0.00%)<br>0    | 0 / 163 (0.00%)<br>0   |
| Gastrointestinal disorders   |                         |                         |                        |
| Diarrhoea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)         | 7 / 185 (3.78%)<br>7    | 10 / 203 (4.93%)<br>13  | 7 / 163 (4.29%)<br>9   |
| Vomiting<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)          | 2 / 185 (1.08%)<br>2    | 1 / 203 (0.49%)<br>1    | 5 / 163 (3.07%)<br>5   |
| Nausea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)            | 4 / 185 (2.16%)<br>5    | 8 / 203 (3.94%)<br>12   | 7 / 163 (4.29%)<br>7   |
| Constipation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)      | 5 / 185 (2.70%)<br>5    | 10 / 203 (4.93%)<br>11  | 3 / 163 (1.84%)<br>4   |
| Skin and subcutaneous tissue disorders   |                         |                         |                        |
| Dermatitis Atopic<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 185 (0.00%)<br>0    | 0 / 203 (0.00%)<br>0    | 0 / 163 (0.00%)<br>0   |
| Rash<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)              | 3 / 185 (1.62%)<br>4    | 0 / 203 (0.00%)<br>0    | 0 / 163 (0.00%)<br>0   |
| Renal and urinary disorders  |                         |                         |                        |
| Urinary Retention<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 42 / 185 (22.70%)<br>50 | 41 / 203 (20.20%)<br>44 | 13 / 163 (7.98%)<br>13 |
| Pollakiuria  |                         |                         |                        |

|   |                                      |                    |                   |
|---|--------------------------------------|--------------------|-------------------|
| subjects affected / exposed                     | 4 / 185 (2.16%)                      | 5 / 203 (2.46%)    | 2 / 163 (1.23%)   |
| occurrences (all)                               | 4                                    | 5                  | 2                 |
| Urine abnormality                               |                                      |                    |                   |
| subjects affected / exposed                     | 1 / 185 (0.54%)                      | 1 / 203 (0.49%)    | 0 / 163 (0.00%)   |
| occurrences (all)                               | 2                                    | 1                  | 0                 |
| Endocrine disorders                             |                                      |                    |                   |
| Hypothyroidism                                  |                                      |                    |                   |
| alternative assessment type: Non-systematic     |                                      |                    |                   |
| subjects affected / exposed                     | 1 / 185 (0.54%)                      | 2 / 203 (0.99%)    | 1 / 163 (0.61%)   |
| occurrences (all)                               | 1                                    | 2                  | 1                 |
| Musculoskeletal and connective tissue disorders |                                      |                    |                   |
| Muscular Weakness                               |                                      |                    |                   |
| alternative assessment type: Non-systematic     |                                      |                    |                   |
| subjects affected / exposed                     | 5 / 185 (2.70%)                      | 8 / 203 (3.94%)    | 10 / 163 (6.13%)  |
| occurrences (all)                               | 6                                    | 10                 | 10                |
| Fracture Pain                                   |                                      |                    |                   |
| alternative assessment type: Non-systematic     |                                      |                    |                   |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%)    | 0 / 163 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                  | 0                 |
| Tendonitis                                      |                                      |                    |                   |
| subjects affected / exposed                     | 0 / 185 (0.00%)                      | 0 / 203 (0.00%)    | 0 / 163 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                  | 0                 |
| Infections and infestations                     |                                      |                    |                   |
| Urinary Tract Infection                         |                                      |                    |                   |
| subjects affected / exposed                     | 100 / 185 (54.05%)                   | 118 / 203 (58.13%) | 86 / 163 (52.76%) |
| occurrences (all)                               | 226                                  | 263                | 177               |
| Nasopharyngitis                                 |                                      |                    |                   |
| alternative assessment type: Non-systematic     |                                      |                    |                   |
| subjects affected / exposed                     | 10 / 185 (5.41%)                     | 9 / 203 (4.43%)    | 7 / 163 (4.29%)   |
| occurrences (all)                               | 12                                   | 12                 | 7                 |
| Vulvovaginal Mycotic Infection                  | Additional description: Females Only |                    |                   |
| alternative assessment type: Non-systematic     |                                      |                    |                   |
| subjects affected / exposed                     | 4 / 185 (2.16%)                      | 7 / 203 (3.45%)    | 4 / 163 (2.45%)   |
| occurrences (all)                               | 4                                    | 7                  | 4                 |
| Upper Respiratory Tract Infection               |                                      |                    |                   |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| alternative assessment type: Non-systematic |                 |                 |                 |
| subjects affected / exposed                 | 7 / 185 (3.78%) | 6 / 203 (2.96%) | 3 / 163 (1.84%) |
| occurrences (all)                           | 10              | 7               | 3               |
| Herpes Zoster                               |                 |                 |                 |
| alternative assessment type: Non-systematic |                 |                 |                 |
| subjects affected / exposed                 | 1 / 185 (0.54%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences (all)                           | 1               | 1               | 0               |
| Fungal Skin Infection                       |                 |                 |                 |
| subjects affected / exposed                 | 1 / 185 (0.54%) | 2 / 203 (0.99%) | 0 / 163 (0.00%) |
| occurrences (all)                           | 1               | 2               | 0               |
| Gastroenteritis Norovirus                   |                 |                 |                 |
| alternative assessment type: Non-systematic |                 |                 |                 |
| subjects affected / exposed                 | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences (all)                           | 0               | 0               | 0               |
| Osteomyelitis Acute                         |                 |                 |                 |
| subjects affected / exposed                 | 0 / 185 (0.00%) | 0 / 203 (0.00%) | 0 / 163 (0.00%) |
| occurrences (all)                           | 0               | 0               | 0               |
| Staphylococcal Infection                    |                 |                 |                 |
| subjects affected / exposed                 | 0 / 185 (0.00%) | 1 / 203 (0.49%) | 0 / 163 (0.00%) |
| occurrences (all)                           | 0               | 1               | 0               |
| Folliculitis                                |                 |                 |                 |
| alternative assessment type: Non-systematic |                 |                 |                 |
| subjects affected / exposed                 | 0 / 185 (0.00%) | 2 / 203 (0.99%) | 0 / 163 (0.00%) |
| occurrences (all)                           | 0               | 2               | 0               |

| <b>Non-serious adverse events</b>                     | Botulinum Toxin Type A 200U Treatment Cycle 2 | Botulinum Toxin Type A 300U Treatment Cycle 3 | Botulinum Toxin Type A 200U Treatment Cycle 3 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |
| subjects affected / exposed                           | 147 / 187 (78.61%)                            | 89 / 119 (74.79%)                             | 123 / 175 (70.29%)                            |
| General disorders and administration site conditions  |   |   |   |
| Oedema Peripheral                                     |   |   |   |
| alternative assessment type: Non-systematic           |   |   |   |
| subjects affected / exposed                           | 3 / 187 (1.60%)                               | 4 / 119 (3.36%)                               | 6 / 175 (3.43%)                               |
| occurrences (all)                                     | 3   | 4   | 6   |
| Fatigue   |   |   |   |
| alternative assessment type: Non-                     |   |   |   |

|  |                                      |                 |                 |
|--|--------------------------------------|-----------------|-----------------|
| systematic                                       |                                      |                 |                 |
| subjects affected / exposed                      | 6 / 187 (3.21%)                      | 3 / 119 (2.52%) | 4 / 175 (2.29%) |
| occurrences (all)                                | 7                                    | 3               | 5               |
| Pyrexia  |                                      |                 |                 |
| alternative assessment type: Non-systematic      |                                      |                 |                 |
| subjects affected / exposed                      | 4 / 187 (2.14%)                      | 2 / 119 (1.68%) | 4 / 175 (2.29%) |
| occurrences (all)                                | 7                                    | 2               | 5               |
| Reproductive system and breast disorders         |                                      |                 |                 |
| Ovarian Cyst                                     | Additional description: Females Only |                 |                 |
| subjects affected / exposed                      | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences (all)                                | 0                                    | 0               | 0               |
| Vulvovaginal Pruritus                            | Additional description: Females Only |                 |                 |
| alternative assessment type: Non-systematic      |                                      |                 |                 |
| subjects affected / exposed                      | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences (all)                                | 0                                    | 0               | 0               |
| Respiratory, thoracic and mediastinal disorders  |                                      |                 |                 |
| Rhinitis Seasonal                                |                                      |                 |                 |
| alternative assessment type: Non-systematic      |                                      |                 |                 |
| subjects affected / exposed                      | 1 / 187 (0.53%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences (all)                                | 1                                    | 0               | 0               |
| Psychiatric disorders                            |                                      |                 |                 |
| Depression                                       |                                      |                 |                 |
| alternative assessment type: Non-systematic      |                                      |                 |                 |
| subjects affected / exposed                      | 5 / 187 (2.67%)                      | 3 / 119 (2.52%) | 0 / 175 (0.00%) |
| occurrences (all)                                | 5                                    | 4               | 0               |
| Investigations                                   |                                      |                 |                 |
| Expanded Disability Status Scale Score Increased |                                      |                 |                 |
| subjects affected / exposed                      | 12 / 187 (6.42%)                     | 4 / 119 (3.36%) | 8 / 175 (4.57%) |
| occurrences (all)                                | 18                                   | 4               | 9               |
| Haemoglobin Decreased                            |                                      |                 |                 |
| subjects affected / exposed                      | 0 / 187 (0.00%)                      | 0 / 119 (0.00%) | 0 / 175 (0.00%) |
| occurrences (all)                                | 0                                    | 0               | 0               |
| Central Nervous System Function Test Abnormal    |                                      |                 |                 |

|  |                      |                      |                      |
|--|----------------------|----------------------|----------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 187 (0.00%)<br>0 | 0 / 119 (0.00%)<br>0 | 0 / 175 (0.00%)<br>0 |
| Injury, poisoning and procedural complications   |                      |                      |                      |
| Fall   |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 6 / 187 (3.21%)      | 1 / 119 (0.84%)      | 9 / 175 (5.14%)      |
| occurrences (all)                                | 7                    | 2                    | 9                    |
| Muscle Strain                                    |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 0 / 187 (0.00%)      | 2 / 119 (1.68%)      | 1 / 175 (0.57%)      |
| occurrences (all)                                | 0                    | 2                    | 1                    |
| Hand Fracture                                    |                      |                      |                      |
| subjects affected / exposed                      | 0 / 187 (0.00%)      | 0 / 119 (0.00%)      | 0 / 175 (0.00%)      |
| occurrences (all)                                | 0                    | 0                    | 0                    |
| Contusion  |                      |                      |                      |
| subjects affected / exposed                      | 1 / 187 (0.53%)      | 0 / 119 (0.00%)      | 1 / 175 (0.57%)      |
| occurrences (all)                                | 1                    | 0                    | 1                    |
| Thermal Burn                                     |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 0 / 187 (0.00%)      | 2 / 119 (1.68%)      | 1 / 175 (0.57%)      |
| occurrences (all)                                | 0                    | 2                    | 1                    |
| Cardiac disorders                                |                      |                      |                      |
| Bundle Branch Block Right                        |                      |                      |                      |
| subjects affected / exposed                      | 0 / 187 (0.00%)      | 0 / 119 (0.00%)      | 0 / 175 (0.00%)      |
| occurrences (all)                                | 0                    | 0                    | 0                    |
| Nervous system disorders                         |                      |                      |                      |
| Muscle Spasticity                                |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 3 / 187 (1.60%)      | 1 / 119 (0.84%)      | 0 / 175 (0.00%)      |
| occurrences (all)                                | 3                    | 1                    | 0                    |
| Headache   |                      |                      |                      |
| alternative assessment type: Non-systematic      |                      |                      |                      |
| subjects affected / exposed                      | 4 / 187 (2.14%)      | 3 / 119 (2.52%)      | 4 / 175 (2.29%)      |
| occurrences (all)                                | 4                    | 3                    | 4                    |
| Blood and lymphatic system disorders             |                      |                      |                      |

|  |                        |                      |                        |
|--|------------------------|----------------------|------------------------|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)   | 1 / 187 (0.53%)<br>1   | 0 / 119 (0.00%)<br>0 | 1 / 175 (0.57%)<br>1   |
| Gastrointestinal disorders   |                        |                      |                        |
| Diarrhoea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)         | 6 / 187 (3.21%)<br>6   | 3 / 119 (2.52%)<br>3 | 1 / 175 (0.57%)<br>1   |
| Vomiting<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)          | 2 / 187 (1.07%)<br>2   | 1 / 119 (0.84%)<br>1 | 4 / 175 (2.29%)<br>5   |
| Nausea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)            | 2 / 187 (1.07%)<br>2   | 3 / 119 (2.52%)<br>3 | 1 / 175 (0.57%)<br>1   |
| Constipation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)      | 5 / 187 (2.67%)<br>6   | 5 / 119 (4.20%)<br>5 | 4 / 175 (2.29%)<br>4   |
| Skin and subcutaneous tissue disorders   |                        |                      |                        |
| Dermatitis Atopic<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 187 (0.00%)<br>0   | 0 / 119 (0.00%)<br>0 | 0 / 175 (0.00%)<br>0   |
| Rash<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)              | 2 / 187 (1.07%)<br>2   | 0 / 119 (0.00%)<br>0 | 1 / 175 (0.57%)<br>1   |
| Renal and urinary disorders  |                        |                      |                        |
| Urinary Retention<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 15 / 187 (8.02%)<br>15 | 8 / 119 (6.72%)<br>9 | 11 / 175 (6.29%)<br>11 |
| Pollakiuria  |                        |                      |                        |



|   |                                      |                          |                          |
|---|--------------------------------------|--------------------------|--------------------------|
| subjects affected / exposed<br>occurrences (all)  | 0 / 187 (0.00%)<br>0                 | 0 / 119 (0.00%)<br>0     | 2 / 175 (1.14%)<br>2     |
| Urine abnormality<br>subjects affected / exposed<br>occurrences (all)   | 1 / 187 (0.53%)<br>1                 | 0 / 119 (0.00%)<br>0     | 0 / 175 (0.00%)<br>0     |
| Endocrine disorders<br>Hypothyroidism<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)                                | 1 / 187 (0.53%)<br>1                 | 1 / 119 (0.84%)<br>1     | 1 / 175 (0.57%)<br>1     |
| Musculoskeletal and connective tissue disorders<br>Muscular Weakness<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 8 / 187 (4.28%)<br>10                | 2 / 119 (1.68%)<br>2     | 6 / 175 (3.43%)<br>8     |
| Fracture Pain<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 0 / 187 (0.00%)<br>0                 | 0 / 119 (0.00%)<br>0     | 0 / 175 (0.00%)<br>0     |
| Tendonitis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 187 (0.00%)<br>0                 | 0 / 119 (0.00%)<br>0     | 0 / 175 (0.00%)<br>0     |
| Infections and infestations<br>Urinary Tract Infection<br>subjects affected / exposed<br>occurrences (all)  | 92 / 187 (49.20%)<br>161             | 61 / 119 (51.26%)<br>111 | 84 / 175 (48.00%)<br>144 |
| Nasopharyngitis<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 5 / 187 (2.67%)<br>5                 | 6 / 119 (5.04%)<br>6     | 1 / 175 (0.57%)<br>1     |
| Vulvovaginal Mycotic Infection<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)                                       | Additional description: Females Only |                          |                          |
| Upper Respiratory Tract Infection   | 5 / 187 (2.67%)<br>6                 | 2 / 119 (1.68%)<br>2     | 3 / 175 (1.71%)<br>4     |

|   |                 |                 |                  |
|---|-----------------|-----------------|------------------|
| alternative assessment type: Non-systematic |                 |                 |                  |
| subjects affected / exposed                 | 2 / 187 (1.07%) | 0 / 119 (0.00%) | 10 / 175 (5.71%) |
| occurrences (all)                           | 2               | 0               | 10               |
| Herpes Zoster                               |                 |                 |                  |
| alternative assessment type: Non-systematic |                 |                 |                  |
| subjects affected / exposed                 | 1 / 187 (0.53%) | 3 / 119 (2.52%) | 1 / 175 (0.57%)  |
| occurrences (all)                           | 1               | 3               | 1                |
| Fungal Skin Infection                       |                 |                 |                  |
| subjects affected / exposed                 | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 1 / 175 (0.57%)  |
| occurrences (all)                           | 0               | 0               | 1                |
| Gastroenteritis Norovirus                   |                 |                 |                  |
| alternative assessment type: Non-systematic |                 |                 |                  |
| subjects affected / exposed                 | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0                |
| Osteomyelitis Acute                         |                 |                 |                  |
| subjects affected / exposed                 | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0                |
| Staphylococcal Infection                    |                 |                 |                  |
| subjects affected / exposed                 | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0                |
| Folliculitis                                |                 |                 |                  |
| alternative assessment type: Non-systematic |                 |                 |                  |
| subjects affected / exposed                 | 0 / 187 (0.00%) | 0 / 119 (0.00%) | 0 / 175 (0.00%)  |
| occurrences (all)                           | 0               | 0               | 0                |

| <b>Non-serious adverse events</b>                     | Botulinum Toxin Type A 300U Treatment Cycle 4 | Botulinum Toxin Type A 200U Treatment Cycle 4 | Botulinum Toxin Type A 300U Treatment Cycle 5 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |
| subjects affected / exposed                           | 51 / 69 (73.91%)                              | 109 / 153 (71.24%)                            | 19 / 34 (55.88%)                              |
| General disorders and administration site conditions  |   |   |   |
| Oedema Peripheral                                     |   |   |   |
| alternative assessment type: Non-systematic           |   |   |   |
| subjects affected / exposed                           | 3 / 69 (4.35%)                                | 2 / 153 (1.31%)                               | 2 / 34 (5.88%)                                |
| occurrences (all)                                     | 3   | 3   | 2   |
| Fatigue   |   |   |   |
| alternative assessment type: Non-                     |   |   |   |

|  |                                      |                 |                |
|--|--------------------------------------|-----------------|----------------|
| systematic                                       |                                      |                 |                |
| subjects affected / exposed                      | 1 / 69 (1.45%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all)                                | 1                                    | 0               | 0              |
| Pyrexia  |                                      |                 |                |
| alternative assessment type: Non-systematic      |                                      |                 |                |
| subjects affected / exposed                      | 0 / 69 (0.00%)                       | 3 / 153 (1.96%) | 0 / 34 (0.00%) |
| occurrences (all)                                | 0                                    | 3               | 0              |
| Reproductive system and breast disorders         |                                      |                 |                |
| Ovarian Cyst                                     | Additional description: Females Only |                 |                |
| subjects affected / exposed                      | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 1 / 34 (2.94%) |
| occurrences (all)                                | 0                                    | 0               | 1              |
| Vulvovaginal Pruritus                            | Additional description: Females Only |                 |                |
| alternative assessment type: Non-systematic      |                                      |                 |                |
| subjects affected / exposed                      | 0 / 69 (0.00%)                       | 1 / 153 (0.65%) | 0 / 34 (0.00%) |
| occurrences (all)                                | 0                                    | 1               | 0              |
| Respiratory, thoracic and mediastinal disorders  |                                      |                 |                |
| Rhinitis Seasonal                                |                                      |                 |                |
| alternative assessment type: Non-systematic      |                                      |                 |                |
| subjects affected / exposed                      | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all)                                | 0                                    | 0               | 0              |
| Psychiatric disorders                            |                                      |                 |                |
| Depression                                       |                                      |                 |                |
| alternative assessment type: Non-systematic      |                                      |                 |                |
| subjects affected / exposed                      | 1 / 69 (1.45%)                       | 1 / 153 (0.65%) | 3 / 34 (8.82%) |
| occurrences (all)                                | 1                                    | 1               | 3              |
| Investigations                                   |                                      |                 |                |
| Expanded Disability Status Scale Score Increased |                                      |                 |                |
| subjects affected / exposed                      | 2 / 69 (2.90%)                       | 5 / 153 (3.27%) | 0 / 34 (0.00%) |
| occurrences (all)                                | 2                                    | 7               | 0              |
| Haemoglobin Decreased                            |                                      |                 |                |
| subjects affected / exposed                      | 0 / 69 (0.00%)                       | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all)                                | 0                                    | 0               | 0              |
| Central Nervous System Function Test Abnormal    |                                      |                 |                |

|  |  |  |  |
|--|--|--|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 69 (0.00%)<br>0  | 0 / 153 (0.00%)<br>0   | 0 / 34 (0.00%)<br>0  |
| Injury, poisoning and procedural complications<br>Fall<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Muscle Strain<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Hand Fracture<br>subjects affected / exposed<br>occurrences (all)<br><br>Contusion<br>subjects affected / exposed<br>occurrences (all)<br><br>Thermal Burn<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 2 / 69 (2.90%)<br>2<br><br>1 / 69 (1.45%)<br>1<br><br>0 / 69 (0.00%)<br>0<br><br>0 / 69 (0.00%)<br>0<br><br>0 / 69 (0.00%)<br>0<br><br>0 / 69 (0.00%)<br>0 | 5 / 153 (3.27%)<br>7<br><br>1 / 153 (0.65%)<br>1<br><br>0 / 153 (0.00%)<br>0<br><br>2 / 153 (1.31%)<br>2<br><br>1 / 153 (0.65%)<br>1 | 0 / 34 (0.00%)<br>0<br><br>0 / 34 (0.00%)<br>0<br><br>0 / 34 (0.00%)<br>0<br><br>1 / 34 (2.94%)<br>1 |
| Cardiac disorders<br>Bundle Branch Block Right<br>subjects affected / exposed<br>occurrences (all)   | 0 / 69 (0.00%)<br>0  | 0 / 153 (0.00%)<br>0   | 0 / 34 (0.00%)<br>0  |
| Nervous system disorders<br>Muscle Spasticity<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 1 / 69 (1.45%)<br>1<br><br>1 / 69 (1.45%)<br>1   | 1 / 153 (0.65%)<br>1<br><br>1 / 153 (0.65%)<br>1   | 2 / 34 (5.88%)<br>3<br><br>1 / 34 (2.94%)<br>1   |
| Blood and lymphatic system disorders   |  |  |  |

|   |  |  |  |
|---|--|--|--|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 69 (0.00%)<br>0  | 0 / 153 (0.00%)<br>0   | 1 / 34 (2.94%)<br>1  |
| Gastrointestinal disorders<br>Diarrhoea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Vomiting<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Nausea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Constipation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 3 / 69 (4.35%)<br>3<br><br>1 / 69 (1.45%)<br>1<br><br>1 / 69 (1.45%)<br>2<br><br>1 / 69 (1.45%)<br>1 | 4 / 153 (2.61%)<br>5<br><br>2 / 153 (1.31%)<br>2<br><br>1 / 153 (0.65%)<br>1<br><br>7 / 153 (4.58%)<br>8 | 2 / 34 (5.88%)<br>2<br><br>1 / 34 (2.94%)<br>1<br><br>0 / 34 (0.00%)<br>0<br><br>0 / 34 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Dermatitis Atopic<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Rash<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 69 (0.00%)<br>0<br><br>1 / 69 (1.45%)<br>1   | 0 / 153 (0.00%)<br>0<br><br>0 / 153 (0.00%)<br>0   | 0 / 34 (0.00%)<br>0<br><br>0 / 34 (0.00%)<br>0   |
| Renal and urinary disorders<br>Urinary Retention<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Pollakiuria  | 0 / 69 (0.00%)<br>0  | 4 / 153 (2.61%)<br>4   | 0 / 34 (0.00%)<br>0  |

|   |                                      |                   |                  |
|---|--------------------------------------|-------------------|------------------|
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 3 / 153 (1.96%)   | 1 / 34 (2.94%)   |
| occurrences (all)                               | 0                                    | 3                 | 1                |
| Urine abnormality                               |                                      |                   |                  |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%)   | 0 / 34 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                 | 0                |
| Endocrine disorders                             |                                      |                   |                  |
| Hypothyroidism                                  |                                      |                   |                  |
| alternative assessment type: Non-systematic     |                                      |                   |                  |
| subjects affected / exposed                     | 1 / 69 (1.45%)                       | 0 / 153 (0.00%)   | 0 / 34 (0.00%)   |
| occurrences (all)                               | 1                                    | 0                 | 0                |
| Musculoskeletal and connective tissue disorders |                                      |                   |                  |
| Muscular Weakness                               |                                      |                   |                  |
| alternative assessment type: Non-systematic     |                                      |                   |                  |
| subjects affected / exposed                     | 2 / 69 (2.90%)                       | 0 / 153 (0.00%)   | 0 / 34 (0.00%)   |
| occurrences (all)                               | 3                                    | 0                 | 0                |
| Fracture Pain                                   |                                      |                   |                  |
| alternative assessment type: Non-systematic     |                                      |                   |                  |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%)   | 0 / 34 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                 | 0                |
| Tendonitis                                      |                                      |                   |                  |
| subjects affected / exposed                     | 0 / 69 (0.00%)                       | 0 / 153 (0.00%)   | 0 / 34 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                 | 0                |
| Infections and infestations                     |                                      |                   |                  |
| Urinary Tract Infection                         |                                      |                   |                  |
| subjects affected / exposed                     | 28 / 69 (40.58%)                     | 60 / 153 (39.22%) | 11 / 34 (32.35%) |
| occurrences (all)                               | 46                                   | 89                | 16               |
| Nasopharyngitis                                 |                                      |                   |                  |
| alternative assessment type: Non-systematic     |                                      |                   |                  |
| subjects affected / exposed                     | 1 / 69 (1.45%)                       | 3 / 153 (1.96%)   | 0 / 34 (0.00%)   |
| occurrences (all)                               | 1                                    | 4                 | 0                |
| Vulvovaginal Mycotic Infection                  | Additional description: Females Only |                   |                  |
| alternative assessment type: Non-systematic     |                                      |                   |                  |
| subjects affected / exposed                     | 1 / 69 (1.45%)                       | 1 / 153 (0.65%)   | 0 / 34 (0.00%)   |
| occurrences (all)                               | 1                                    | 2                 | 0                |
| Upper Respiratory Tract Infection               |                                      |                   |                  |

|   |                |                 |                |
|---|----------------|-----------------|----------------|
| alternative assessment type: Non-systematic |                |                 |                |
| subjects affected / exposed                 | 1 / 69 (1.45%) | 2 / 153 (1.31%) | 0 / 34 (0.00%) |
| occurrences (all)                           | 1              | 2               | 0              |
| Herpes Zoster                               |                |                 |                |
| alternative assessment type: Non-systematic |                |                 |                |
| subjects affected / exposed                 | 1 / 69 (1.45%) | 2 / 153 (1.31%) | 0 / 34 (0.00%) |
| occurrences (all)                           | 1              | 2               | 0              |
| Fungal Skin Infection                       |                |                 |                |
| subjects affected / exposed                 | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all)                           | 0              | 0               | 0              |
| Gastroenteritis Norovirus                   |                |                 |                |
| alternative assessment type: Non-systematic |                |                 |                |
| subjects affected / exposed                 | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all)                           | 0              | 0               | 0              |
| Osteomyelitis Acute                         |                |                 |                |
| subjects affected / exposed                 | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all)                           | 0              | 0               | 0              |
| Staphylococcal Infection                    |                |                 |                |
| subjects affected / exposed                 | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 0 / 34 (0.00%) |
| occurrences (all)                           | 0              | 0               | 0              |
| Folliculitis                                |                |                 |                |
| alternative assessment type: Non-systematic |                |                 |                |
| subjects affected / exposed                 | 0 / 69 (0.00%) | 0 / 153 (0.00%) | 1 / 34 (2.94%) |
| occurrences (all)                           | 0              | 0               | 1              |

| <b>Non-serious adverse events</b>                     | Botulinum Toxin Type A 200U Treatment Cycle 5 | Botulinum Toxin Type A 300U Treatment Cycle 6 | Botulinum Toxin Type A 200U Treatment Cycle 6 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |
| subjects affected / exposed                           | 72 / 110 (65.45%)                             | 8 / 16 (50.00%)                               | 46 / 70 (65.71%)                              |
| General disorders and administration site conditions  |   |   |   |
| Oedema Peripheral                                     |   |   |   |
| alternative assessment type: Non-systematic           |   |   |   |
| subjects affected / exposed                           | 1 / 110 (0.91%)                               | 0 / 16 (0.00%)                                | 2 / 70 (2.86%)                                |
| occurrences (all)                                     | 1   | 0   | 2   |
| Fatigue   |   |   |   |
| alternative assessment type: Non-                     |   |   |   |

|  |                                      |                |                |
|--|--------------------------------------|----------------|----------------|
| systematic                                       |                                      |                |                |
| subjects affected / exposed                      | 2 / 110 (1.82%)                      | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences (all)                                | 2                                    | 0              | 1              |
| Pyrexia  |                                      |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 1 / 110 (0.91%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                                | 1                                    | 0              | 0              |
| Reproductive system and breast disorders         |                                      |                |                |
| Ovarian Cyst                                     | Additional description: Females Only |                |                |
| subjects affected / exposed                      | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0              |
| Vulvovaginal Pruritus                            | Additional description: Females Only |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 1 / 110 (0.91%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                                | 1                                    | 0              | 0              |
| Respiratory, thoracic and mediastinal disorders  |                                      |                |                |
| Rhinitis Seasonal                                |                                      |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0              |
| Psychiatric disorders                            |                                      |                |                |
| Depression                                       |                                      |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 1 / 110 (0.91%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                                | 1                                    | 0              | 0              |
| Investigations                                   |                                      |                |                |
| Expanded Disability Status Scale Score Increased |                                      |                |                |
| subjects affected / exposed                      | 3 / 110 (2.73%)                      | 0 / 16 (0.00%) | 1 / 70 (1.43%) |
| occurrences (all)                                | 3                                    | 0              | 1              |
| Haemoglobin Decreased                            |                                      |                |                |
| subjects affected / exposed                      | 0 / 110 (0.00%)                      | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0              |
| Central Nervous System Function Test Abnormal    |                                      |                |                |



|  |  |   |   |
|--|--|---|---|
| subjects affected / exposed<br>occurrences (all)   | 0 / 110 (0.00%)<br>0   | 0 / 16 (0.00%)<br>0   | 0 / 70 (0.00%)<br>0   |
| Injury, poisoning and procedural complications<br>Fall<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Muscle Strain<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Hand Fracture<br>subjects affected / exposed<br>occurrences (all)<br><br>Contusion<br>subjects affected / exposed<br>occurrences (all)<br><br>Thermal Burn<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 4 / 110 (3.64%)<br>4<br><br>0 / 110 (0.00%)<br>0<br><br>0 / 110 (0.00%)<br>0<br><br>0 / 110 (0.00%)<br>0<br><br>0 / 110 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0<br><br>1 / 16 (6.25%)<br>1<br><br>1 / 16 (6.25%)<br>1<br><br>0 / 16 (0.00%)<br>0<br><br>0 / 16 (0.00%)<br>0 | 3 / 70 (4.29%)<br>3<br><br>1 / 70 (1.43%)<br>1<br><br>0 / 70 (0.00%)<br>0<br><br>0 / 70 (0.00%)<br>0<br><br>0 / 70 (0.00%)<br>0 |
| Cardiac disorders<br>Bundle Branch Block Right<br>subjects affected / exposed<br>occurrences (all)   | 0 / 110 (0.00%)<br>0   | 0 / 16 (0.00%)<br>0   | 0 / 70 (0.00%)<br>0   |
| Nervous system disorders<br>Muscle Spasticity<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 0 / 110 (0.00%)<br>0<br><br>3 / 110 (2.73%)<br>3   | 1 / 16 (6.25%)<br>1<br><br>0 / 16 (0.00%)<br>0  | 1 / 70 (1.43%)<br>1<br><br>2 / 70 (2.86%)<br>2  |
| Blood and lymphatic system disorders   |  |   |   |

|  |                      |                     |                     |
|--|----------------------|---------------------|---------------------|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)   | 0 / 110 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0 | 1 / 70 (1.43%)<br>1 |
| Gastrointestinal disorders   |                      |                     |                     |
| Diarrhoea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)         | 4 / 110 (3.64%)<br>4 | 0 / 16 (0.00%)<br>0 | 4 / 70 (5.71%)<br>5 |
| Vomiting<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)          | 3 / 110 (2.73%)<br>4 | 1 / 16 (6.25%)<br>1 | 2 / 70 (2.86%)<br>2 |
| Nausea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)            | 3 / 110 (2.73%)<br>3 | 1 / 16 (6.25%)<br>1 | 1 / 70 (1.43%)<br>1 |
| Constipation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)      | 4 / 110 (3.64%)<br>5 | 0 / 16 (0.00%)<br>0 | 1 / 70 (1.43%)<br>1 |
| Skin and subcutaneous tissue disorders   |                      |                     |                     |
| Dermatitis Atopic<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 110 (0.00%)<br>0 | 0 / 16 (0.00%)<br>0 | 0 / 70 (0.00%)<br>0 |
| Rash<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)              | 1 / 110 (0.91%)<br>1 | 0 / 16 (0.00%)<br>0 | 1 / 70 (1.43%)<br>1 |
| Renal and urinary disorders  |                      |                     |                     |
| Urinary Retention<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 2 / 110 (1.82%)<br>3 | 0 / 16 (0.00%)<br>0 | 0 / 70 (0.00%)<br>0 |
| Pollakiuria  |                      |                     |                     |

|   |                                      |                 |                  |
|---|--------------------------------------|-----------------|------------------|
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%)  | 0 / 70 (0.00%)   |
| occurrences (all)                               | 0                                    | 0               | 0                |
| Urine abnormality                               |                                      |                 |                  |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%)  | 0 / 70 (0.00%)   |
| occurrences (all)                               | 0                                    | 0               | 0                |
| Endocrine disorders                             |                                      |                 |                  |
| Hypothyroidism                                  |                                      |                 |                  |
| alternative assessment type: Non-systematic     |                                      |                 |                  |
| subjects affected / exposed                     | 1 / 110 (0.91%)                      | 0 / 16 (0.00%)  | 0 / 70 (0.00%)   |
| occurrences (all)                               | 1                                    | 0               | 0                |
| Musculoskeletal and connective tissue disorders |                                      |                 |                  |
| Muscular Weakness                               |                                      |                 |                  |
| alternative assessment type: Non-systematic     |                                      |                 |                  |
| subjects affected / exposed                     | 2 / 110 (1.82%)                      | 0 / 16 (0.00%)  | 2 / 70 (2.86%)   |
| occurrences (all)                               | 2                                    | 0               | 2                |
| Fracture Pain                                   |                                      |                 |                  |
| alternative assessment type: Non-systematic     |                                      |                 |                  |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 1 / 16 (6.25%)  | 0 / 70 (0.00%)   |
| occurrences (all)                               | 0                                    | 1               | 0                |
| Tendonitis                                      |                                      |                 |                  |
| subjects affected / exposed                     | 1 / 110 (0.91%)                      | 1 / 16 (6.25%)  | 0 / 70 (0.00%)   |
| occurrences (all)                               | 1                                    | 1               | 0                |
| Infections and infestations                     |                                      |                 |                  |
| Urinary Tract Infection                         |                                      |                 |                  |
| subjects affected / exposed                     | 35 / 110 (31.82%)                    | 4 / 16 (25.00%) | 21 / 70 (30.00%) |
| occurrences (all)                               | 58                                   | 5               | 32               |
| Nasopharyngitis                                 |                                      |                 |                  |
| alternative assessment type: Non-systematic     |                                      |                 |                  |
| subjects affected / exposed                     | 2 / 110 (1.82%)                      | 0 / 16 (0.00%)  | 0 / 70 (0.00%)   |
| occurrences (all)                               | 2                                    | 0               | 0                |
| Vulvovaginal Mycotic Infection                  | Additional description: Females Only |                 |                  |
| alternative assessment type: Non-systematic     |                                      |                 |                  |
| subjects affected / exposed                     | 0 / 110 (0.00%)                      | 0 / 16 (0.00%)  | 1 / 70 (1.43%)   |
| occurrences (all)                               | 0                                    | 0               | 1                |
| Upper Respiratory Tract Infection               |                                      |                 |                  |

|   |                 |                |                |
|---|-----------------|----------------|----------------|
| alternative assessment type: Non-systematic |                 |                |                |
| subjects affected / exposed                 | 2 / 110 (1.82%) | 1 / 16 (6.25%) | 0 / 70 (0.00%) |
| occurrences (all)                           | 2               | 1              | 1              |
| Herpes Zoster                               |                 |                |                |
| alternative assessment type: Non-systematic |                 |                |                |
| subjects affected / exposed                 | 2 / 110 (1.82%) | 0 / 16 (0.00%) | 2 / 70 (2.86%) |
| occurrences (all)                           | 2               | 0              | 2              |
| Fungal Skin Infection                       |                 |                |                |
| subjects affected / exposed                 | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                           | 0               | 0              | 0              |
| Gastroenteritis Norovirus                   |                 |                |                |
| alternative assessment type: Non-systematic |                 |                |                |
| subjects affected / exposed                 | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                           | 0               | 0              | 0              |
| Osteomyelitis Acute                         |                 |                |                |
| subjects affected / exposed                 | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                           | 0               | 0              | 0              |
| Staphylococcal Infection                    |                 |                |                |
| subjects affected / exposed                 | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                           | 0               | 0              | 0              |
| Folliculitis                                |                 |                |                |
| alternative assessment type: Non-systematic |                 |                |                |
| subjects affected / exposed                 | 0 / 110 (0.00%) | 0 / 16 (0.00%) | 0 / 70 (0.00%) |
| occurrences (all)                           | 0               | 0              | 0              |

| <b>Non-serious adverse events</b>                     | Botulinum Toxin Type A 300U Treatment Cycle 7 | Botulinum Toxin Type A 200U Treatment Cycle 7 | Botulinum Toxin Type A 200U Treatment Cycle 8 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events |   |   |   |
| subjects affected / exposed                           | 3 / 8 (37.50%)                                | 28 / 48 (58.33%)                              | 23 / 36 (63.89%)                              |
| General disorders and administration site conditions  |   |   |   |
| Oedema Peripheral                                     |   |   |   |
| alternative assessment type: Non-systematic           |   |   |   |
| subjects affected / exposed                           | 0 / 8 (0.00%)                                 | 2 / 48 (4.17%)                                | 2 / 36 (5.56%)                                |
| occurrences (all)                                     | 0   | 2   | 2   |
| Fatigue   |   |   |   |
| alternative assessment type: Non-                     |   |   |   |

|  |                                      |                |                |
|--|--------------------------------------|----------------|----------------|
| systematic                                       |                                      |                |                |
| subjects affected / exposed                      | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all)                                | 0                                    | 0              | 1              |
| Pyrexia  |                                      |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 0 / 8 (0.00%)                        | 2 / 48 (4.17%) | 1 / 36 (2.78%) |
| occurrences (all)                                | 0                                    | 2              | 2              |
| Reproductive system and breast disorders         |                                      |                |                |
| Ovarian Cyst                                     | Additional description: Females Only |                |                |
| subjects affected / exposed                      | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0              |
| Vulvovaginal Pruritus                            | Additional description: Females Only |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 1 / 36 (2.78%) |
| occurrences (all)                                | 0                                    | 0              | 1              |
| Respiratory, thoracic and mediastinal disorders  |                                      |                |                |
| Rhinitis Seasonal                                |                                      |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0              |
| Psychiatric disorders                            |                                      |                |                |
| Depression                                       |                                      |                |                |
| alternative assessment type: Non-systematic      |                                      |                |                |
| subjects affected / exposed                      | 0 / 8 (0.00%)                        | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0              |
| Investigations                                   |                                      |                |                |
| Expanded Disability Status Scale Score Increased |                                      |                |                |
| subjects affected / exposed                      | 0 / 8 (0.00%)                        | 1 / 48 (2.08%) | 2 / 36 (5.56%) |
| occurrences (all)                                | 0                                    | 2              | 2              |
| Haemoglobin Decreased                            |                                      |                |                |
| subjects affected / exposed                      | 1 / 8 (12.50%)                       | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                                | 1                                    | 0              | 0              |
| Central Nervous System Function Test Abnormal    |                                      |                |                |

|  |  |   |  |
|--|--|---|--|
| subjects affected / exposed<br>occurrences (all)   | 0 / 8 (0.00%)<br>0   | 0 / 48 (0.00%)<br>0   | 0 / 36 (0.00%)<br>0  |
| Injury, poisoning and procedural complications<br>Fall<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Muscle Strain<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Hand Fracture<br>subjects affected / exposed<br>occurrences (all)<br><br>Contusion<br>subjects affected / exposed<br>occurrences (all)<br><br>Thermal Burn<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0 | 3 / 48 (6.25%)<br>7<br><br>0 / 48 (0.00%)<br>0<br><br>0 / 48 (0.00%)<br>0<br><br>3 / 48 (6.25%)<br>3<br><br>0 / 48 (0.00%)<br>0 | 3 / 36 (8.33%)<br>6<br><br>0 / 36 (0.00%)<br>0<br><br>0 / 36 (0.00%)<br>0<br><br>0 / 36 (0.00%)<br>0 |
| Cardiac disorders<br>Bundle Branch Block Right<br>subjects affected / exposed<br>occurrences (all)   | 0 / 8 (0.00%)<br>0   | 0 / 48 (0.00%)<br>0   | 0 / 36 (0.00%)<br>0  |
| Nervous system disorders<br>Muscle Spasticity<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0   | 1 / 48 (2.08%)<br>1<br><br>1 / 48 (2.08%)<br>1  | 1 / 36 (2.78%)<br>1<br><br>2 / 36 (5.56%)<br>2   |
| Blood and lymphatic system disorders   |  |   |  |

|   |  |  |  |
|---|--|--|--|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 8 (0.00%)<br>0   | 0 / 48 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0  |
| Gastrointestinal disorders<br>Diarrhoea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Vomiting<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Nausea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Constipation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0 | 3 / 48 (6.25%)<br>4<br><br>0 / 48 (0.00%)<br>0<br><br>1 / 48 (2.08%)<br>1<br><br>3 / 48 (6.25%)<br>3 | 0 / 36 (0.00%)<br>0<br><br>1 / 36 (2.78%)<br>2<br><br>1 / 36 (2.78%)<br>2<br><br>1 / 36 (2.78%)<br>1 |
| Skin and subcutaneous tissue disorders<br>Dermatitis Atopic<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Rash<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 8 (0.00%)<br>0<br><br>0 / 8 (0.00%)<br>0   | 0 / 48 (0.00%)<br>0<br><br>1 / 48 (2.08%)<br>1   | 0 / 36 (0.00%)<br>0<br><br>1 / 36 (2.78%)<br>1   |
| Renal and urinary disorders<br>Urinary Retention<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Pollakiuria  | 0 / 8 (0.00%)<br>0   | 0 / 48 (0.00%)<br>0  | 0 / 36 (0.00%)<br>0  |

|   |                                      |                  |                  |
|---|--------------------------------------|------------------|------------------|
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%)   | 0 / 36 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                | 0                |
| Urine abnormality                               |                                      |                  |                  |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%)   | 0 / 36 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                | 0                |
| Endocrine disorders                             |                                      |                  |                  |
| Hypothyroidism                                  |                                      |                  |                  |
| alternative assessment type: Non-systematic     |                                      |                  |                  |
| subjects affected / exposed                     | 1 / 8 (12.50%)                       | 1 / 48 (2.08%)   | 0 / 36 (0.00%)   |
| occurrences (all)                               | 1                                    | 1                | 0                |
| Musculoskeletal and connective tissue disorders |                                      |                  |                  |
| Muscular Weakness                               |                                      |                  |                  |
| alternative assessment type: Non-systematic     |                                      |                  |                  |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 1 / 48 (2.08%)   | 1 / 36 (2.78%)   |
| occurrences (all)                               | 0                                    | 1                | 1                |
| Fracture Pain                                   |                                      |                  |                  |
| alternative assessment type: Non-systematic     |                                      |                  |                  |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%)   | 0 / 36 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                | 0                |
| Tendonitis                                      |                                      |                  |                  |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%)   | 0 / 36 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                | 0                |
| Infections and infestations                     |                                      |                  |                  |
| Urinary Tract Infection                         |                                      |                  |                  |
| subjects affected / exposed                     | 3 / 8 (37.50%)                       | 15 / 48 (31.25%) | 12 / 36 (33.33%) |
| occurrences (all)                               | 6                                    | 19               | 20               |
| Nasopharyngitis                                 |                                      |                  |                  |
| alternative assessment type: Non-systematic     |                                      |                  |                  |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 1 / 48 (2.08%)   | 1 / 36 (2.78%)   |
| occurrences (all)                               | 0                                    | 1                | 1                |
| Vulvovaginal Mycotic Infection                  | Additional description: Females Only |                  |                  |
| alternative assessment type: Non-systematic     |                                      |                  |                  |
| subjects affected / exposed                     | 0 / 8 (0.00%)                        | 0 / 48 (0.00%)   | 0 / 36 (0.00%)   |
| occurrences (all)                               | 0                                    | 0                | 0                |
| Upper Respiratory Tract Infection               |                                      |                  |                  |



|   |                |                |                |
|---|----------------|----------------|----------------|
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 0 / 8 (0.00%)  | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Herpes Zoster                               |                |                |                |
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 1 / 8 (12.50%) | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                           | 1              | 0              | 0              |
| Fungal Skin Infection                       |                |                |                |
| subjects affected / exposed                 | 0 / 8 (0.00%)  | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Gastroenteritis Norovirus                   |                |                |                |
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 0 / 8 (0.00%)  | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Osteomyelitis Acute                         |                |                |                |
| subjects affected / exposed                 | 0 / 8 (0.00%)  | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Staphylococcal Infection                    |                |                |                |
| subjects affected / exposed                 | 0 / 8 (0.00%)  | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |
| Folliculitis                                |                |                |                |
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 0 / 8 (0.00%)  | 0 / 48 (0.00%) | 0 / 36 (0.00%) |
| occurrences (all)                           | 0              | 0              | 0              |

| <b>Non-serious adverse events</b>                     | Botulinum Toxin Type A 200U Treatment Cycle 9 | Botulinum Toxin Type A 200U Treatment Cycle 10 | Botulinum Toxin Type A 200U Treatment Cycle 11 |
|---|---|--|--|
| Total subjects affected by non-serious adverse events |   |  |  |
| subjects affected / exposed                           | 13 / 22 (59.09%)                              | 5 / 11 (45.45%)                                | 3 / 5 (60.00%)                                 |
| General disorders and administration site conditions  |   |  |  |
| Oedema Peripheral                                     |   |  |  |
| alternative assessment type: Non-systematic           |   |  |  |
| subjects affected / exposed                           | 1 / 22 (4.55%)                                | 0 / 11 (0.00%)                                 | 0 / 5 (0.00%)                                  |
| occurrences (all)                                     | 1   | 0  | 0  |
| Fatigue   |   |  |  |
| alternative assessment type: Non-                     |   |  |  |

|  |                                      |                |               |
|--|--------------------------------------|----------------|---------------|
| systematic                                       |                                      |                |               |
| subjects affected / exposed                      | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0             |
| Pyrexia  |                                      |                |               |
| alternative assessment type: Non-systematic      |                                      |                |               |
| subjects affected / exposed                      | 1 / 22 (4.55%)                       | 1 / 11 (9.09%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 1                                    | 1              | 0             |
| Reproductive system and breast disorders         |                                      |                |               |
| Ovarian Cyst                                     | Additional description: Females Only |                |               |
| subjects affected / exposed                      | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0             |
| Vulvovaginal Pruritus                            | Additional description: Females Only |                |               |
| alternative assessment type: Non-systematic      |                                      |                |               |
| subjects affected / exposed                      | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0             |
| Respiratory, thoracic and mediastinal disorders  |                                      |                |               |
| Rhinitis Seasonal                                |                                      |                |               |
| alternative assessment type: Non-systematic      |                                      |                |               |
| subjects affected / exposed                      | 0 / 22 (0.00%)                       | 1 / 11 (9.09%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 0                                    | 1              | 0             |
| Psychiatric disorders                            |                                      |                |               |
| Depression                                       |                                      |                |               |
| alternative assessment type: Non-systematic      |                                      |                |               |
| subjects affected / exposed                      | 1 / 22 (4.55%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 1                                    | 0              | 0             |
| Investigations                                   |                                      |                |               |
| Expanded Disability Status Scale Score Increased |                                      |                |               |
| subjects affected / exposed                      | 1 / 22 (4.55%)                       | 1 / 11 (9.09%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 1                                    | 1              | 0             |
| Haemoglobin Decreased                            |                                      |                |               |
| subjects affected / exposed                      | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%) |
| occurrences (all)                                | 0                                    | 0              | 0             |
| Central Nervous System Function Test Abnormal    |                                      |                |               |

|  |   |   |   |
|--|---|---|---|
| subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0   | 1 / 11 (9.09%)<br>1   | 0 / 5 (0.00%)<br>0  |
| Injury, poisoning and procedural complications<br>Fall<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Muscle Strain<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Hand Fracture<br>subjects affected / exposed<br>occurrences (all)<br><br>Contusion<br>subjects affected / exposed<br>occurrences (all)<br><br>Thermal Burn<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 1 / 22 (4.55%)<br>1<br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0<br><br>1 / 22 (4.55%)<br>1<br><br>0 / 22 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>1 / 5 (20.00%)<br>1 |
| Cardiac disorders<br>Bundle Branch Block Right<br>subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0   | 1 / 11 (9.09%)<br>1   | 0 / 5 (0.00%)<br>0  |
| Nervous system disorders<br>Muscle Spasticity<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Headache<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0  | 0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0  | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0  |
| Blood and lymphatic system disorders   |   |   |   |

|   |   |   |  |
|---|---|---|--|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 22 (0.00%)<br>0   | 1 / 11 (9.09%)<br>1   | 0 / 5 (0.00%)<br>0   |
| Gastrointestinal disorders<br>Diarrhoea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Vomiting<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Nausea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Constipation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0 | 0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0<br><br>0 / 11 (0.00%)<br>0 | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0 |
| Skin and subcutaneous tissue disorders<br>Dermatitis Atopic<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Rash<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 22 (0.00%)<br>0<br><br>0 / 22 (0.00%)<br>0  | 1 / 11 (9.09%)<br>1<br><br>1 / 11 (9.09%)<br>1  | 0 / 5 (0.00%)<br>0<br><br>0 / 5 (0.00%)<br>0   |
| Renal and urinary disorders<br>Urinary Retention<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Pollakiuria  | 0 / 22 (0.00%)<br>0   | 0 / 11 (0.00%)<br>0   | 0 / 5 (0.00%)<br>0   |

|   |                                      |                |                |
|---|--------------------------------------|----------------|----------------|
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all)                               | 0                                    | 0              | 1              |
| Urine abnormality                               |                                      |                |                |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all)                               | 0                                    | 0              | 1              |
| Endocrine disorders                             |                                      |                |                |
| Hypothyroidism                                  |                                      |                |                |
| alternative assessment type: Non-systematic     |                                      |                |                |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                               | 0                                    | 0              | 0              |
| Musculoskeletal and connective tissue disorders |                                      |                |                |
| Muscular Weakness                               |                                      |                |                |
| alternative assessment type: Non-systematic     |                                      |                |                |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                               | 0                                    | 0              | 0              |
| Fracture Pain                                   |                                      |                |                |
| alternative assessment type: Non-systematic     |                                      |                |                |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                               | 0                                    | 0              | 0              |
| Tendonitis                                      |                                      |                |                |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                               | 0                                    | 0              | 0              |
| Infections and infestations                     |                                      |                |                |
| Urinary Tract Infection                         |                                      |                |                |
| subjects affected / exposed                     | 7 / 22 (31.82%)                      | 1 / 11 (9.09%) | 1 / 5 (20.00%) |
| occurrences (all)                               | 11                                   | 2              | 1              |
| Nasopharyngitis                                 |                                      |                |                |
| alternative assessment type: Non-systematic     |                                      |                |                |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                               | 0                                    | 0              | 0              |
| Vulvovaginal Mycotic Infection                  | Additional description: Females Only |                |                |
| alternative assessment type: Non-systematic     |                                      |                |                |
| subjects affected / exposed                     | 0 / 22 (0.00%)                       | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                               | 0                                    | 0              | 0              |
| Upper Respiratory Tract Infection               |                                      |                |                |

|   |                |                |                |
|---|----------------|----------------|----------------|
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Herpes Zoster                               |                |                |                |
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 0              | 0              |
| Fungal Skin Infection                       |                |                |                |
| subjects affected / exposed                 | 0 / 22 (0.00%) | 1 / 11 (9.09%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 1              | 0              |
| Gastroenteritis Norovirus                   |                |                |                |
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 0 / 22 (0.00%) | 1 / 11 (9.09%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 1              | 0              |
| Osteomyelitis Acute                         |                |                |                |
| subjects affected / exposed                 | 0 / 22 (0.00%) | 1 / 11 (9.09%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 1              | 0              |
| Staphylococcal Infection                    |                |                |                |
| subjects affected / exposed                 | 0 / 22 (0.00%) | 1 / 11 (9.09%) | 0 / 5 (0.00%)  |
| occurrences (all)                           | 0              | 1              | 0              |
| Folliculitis                                |                |                |                |
| alternative assessment type: Non-systematic |                |                |                |
| subjects affected / exposed                 | 0 / 22 (0.00%) | 0 / 11 (0.00%) | 1 / 5 (20.00%) |
| occurrences (all)                           | 0              | 0              | 1              |

|   |  |  |  |
|---|--|--|--|
| <b>Non-serious adverse events</b>                     | Botulinum Toxin Type A 200U Treatment Cycle 12 |  |  |
| Total subjects affected by non-serious adverse events |  |  |  |
| subjects affected / exposed                           | 1 / 2 (50.00%)                                 |  |  |
| General disorders and administration site conditions  |  |  |  |
| Oedema Peripheral                                     |  |  |  |
| alternative assessment type: Non-systematic           |  |  |  |
| subjects affected / exposed                           | 0 / 2 (0.00%)                                  |  |  |
| occurrences (all)                                     | 0  |  |  |
| Fatigue   |  |  |  |
| alternative assessment type: Non-                     |  |  |  |

|  |                                      |  |  |
|--|--------------------------------------|--|--|
| systematic                                       |                                      |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Pyrexia  |                                      |  |  |
| alternative assessment type: Non-systematic      |                                      |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Reproductive system and breast disorders         |                                      |  |  |
| Ovarian Cyst                                     | Additional description: Females Only |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Vulvovaginal Pruritus                            | Additional description: Females Only |  |  |
| alternative assessment type: Non-systematic      |                                      |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Respiratory, thoracic and mediastinal disorders  |                                      |  |  |
| Rhinitis Seasonal                                |                                      |  |  |
| alternative assessment type: Non-systematic      |                                      |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Psychiatric disorders                            |                                      |  |  |
| Depression                                       |                                      |  |  |
| alternative assessment type: Non-systematic      |                                      |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Investigations                                   |                                      |  |  |
| Expanded Disability Status Scale Score Increased |                                      |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Haemoglobin Decreased                            |                                      |  |  |
| subjects affected / exposed                      | 0 / 2 (0.00%)                        |  |  |
| occurrences (all)                                | 0                                    |  |  |
| Central Nervous System Function Test Abnormal    |                                      |  |  |

|  |               |  |  |
|--|---------------|--|--|
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Injury, poisoning and procedural complications |               |  |  |
| Fall   |               |  |  |
| alternative assessment type: Non-systematic    |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Muscle Strain                                  |               |  |  |
| alternative assessment type: Non-systematic    |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Hand Fracture                                  |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Contusion                                      |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Thermal Burn                                   |               |  |  |
| alternative assessment type: Non-systematic    |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Cardiac disorders                              |               |  |  |
| Bundle Branch Block Right                      |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Nervous system disorders                       |               |  |  |
| Muscle Spasticity                              |               |  |  |
| alternative assessment type: Non-systematic    |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Headache                                       |               |  |  |
| alternative assessment type: Non-systematic    |               |  |  |
| subjects affected / exposed                    | 0 / 2 (0.00%) |  |  |
| occurrences (all)                              | 0             |  |  |
| Blood and lymphatic system disorders           |               |  |  |



|   |  |  |  |
|---|--|--|--|
| Leukocytosis<br>subjects affected / exposed<br>occurrences (all)  | 0 / 2 (0.00%)<br>0   |  |  |
| Gastrointestinal disorders<br>Diarrhoea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Vomiting<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Nausea<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Constipation<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all) | 0 / 2 (0.00%)<br>0<br><br><br><br>0 / 2 (0.00%)<br>0<br><br><br>0 / 2 (0.00%)<br>0<br><br><br>0 / 2 (0.00%)<br>0 |  |  |
| Skin and subcutaneous tissue disorders<br>Dermatitis Atopic<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Rash<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 2 (0.00%)<br>0<br><br><br>1 / 2 (50.00%)<br>1  |  |  |
| Renal and urinary disorders<br>Urinary Retention<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Pollakiuria  | 0 / 2 (0.00%)<br>0   |  |  |

|   |  |  |  |
|---|--|--|--|
| subjects affected / exposed<br>occurrences (all)<br><br>Urine abnormality<br>subjects affected / exposed<br>occurrences (all)   | 1 / 2 (50.00%)<br><br>1<br><br>1 / 2 (50.00%)<br><br>1                             |  |  |
| Endocrine disorders<br>Hypothyroidism<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 0 / 2 (0.00%)<br><br>0   |  |  |
| Musculoskeletal and connective tissue disorders<br>Muscular Weakness<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Fracture Pain<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)<br><br>Tendonitis<br>subjects affected / exposed<br>occurrences (all) | 0 / 2 (0.00%)<br><br>0<br><br>0 / 2 (0.00%)<br><br>0<br><br>0 / 2 (0.00%)<br><br>0 |  |  |
| Infections and infestations<br>Urinary Tract Infection<br>subjects affected / exposed<br>occurrences (all)<br><br>Nasopharyngitis<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)  | 1 / 2 (50.00%)<br><br>1<br><br>0 / 2 (0.00%)<br><br>0                              |  |  |
| Vulvovaginal Mycotic Infection<br>alternative assessment type: Non-systematic<br>subjects affected / exposed<br>occurrences (all)   | 0 / 2 (0.00%)<br><br>0   |  |  |
| Upper Respiratory Tract Infection   |  |  |  |

|   |               |  |  |
|---|---------------|--|--|
| alternative assessment type: Non-systematic |               |  |  |
| subjects affected / exposed                 | 0 / 2 (0.00%) |  |  |
| occurrences (all)                           | 0             |  |  |
| Herpes Zoster                               |               |  |  |
| alternative assessment type: Non-systematic |               |  |  |
| subjects affected / exposed                 | 0 / 2 (0.00%) |  |  |
| occurrences (all)                           | 0             |  |  |
| Fungal Skin Infection                       |               |  |  |
| subjects affected / exposed                 | 0 / 2 (0.00%) |  |  |
| occurrences (all)                           | 0             |  |  |
| Gastroenteritis Norovirus                   |               |  |  |
| alternative assessment type: Non-systematic |               |  |  |
| subjects affected / exposed                 | 0 / 2 (0.00%) |  |  |
| occurrences (all)                           | 0             |  |  |
| Osteomyelitis Acute                         |               |  |  |
| subjects affected / exposed                 | 0 / 2 (0.00%) |  |  |
| occurrences (all)                           | 0             |  |  |
| Staphylococcal Infection                    |               |  |  |
| subjects affected / exposed                 | 0 / 2 (0.00%) |  |  |
| occurrences (all)                           | 0             |  |  |
| Folliculitis                                |               |  |  |
| alternative assessment type: Non-systematic |               |  |  |
| subjects affected / exposed                 | 0 / 2 (0.00%) |  |  |
| occurrences (all)                           | 0             |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment  |
|------------------|--|
| 01 November 2009 | Collection of hematology and blood chemistry samples was added at week-12.   |
| 01 March 2011    | 1) The 300 U BOTOX dose group was removed from the protocol; 2) It was clarified that the latest time study treatment could be administered was week 144; and 3) It was clarified that the responder analysis included a cut-off of 100% and references to analysis of these data were removed, as the information from the responder analysis would be summarized only. |
| 01 July 2012     | Optional urodynamic assessments were to be done at sites that agreed to perform them and for those patients who agreed to undergo the procedure.   |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported