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 Idiopathic Overactive Bladder with Urinary Incontinence

Summary

EudraCT number	2009-013089-26
Trial protocol	GB BE DE CZ PL
Global end of trial date	05 August 2014

Results information

Result version number	v1 (current)
This version publication date	18 September 2016
First version publication date	18 September 2016

Trial information

Trial identification

Sponsor protocol code	191622-096

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00915525
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	05 August 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 August 2014
Global end of trial reached?	Yes
Global end of trial date	05 August 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the long-term safety and efficacy of BOTOX in patients with idiopathic OAB with urinary incontinence whose symptoms had 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	29 March 2010
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	Belgium: 48
Country: Number of subjects enrolled	Canada: 61
Country: Number of subjects enrolled	Czech Republic: 61
Country: Number of subjects enrolled	United Kingdom: 24
Country: Number of subjects enrolled	Poland: 57
Country: Number of subjects enrolled	Russian Federation: 65
Country: Number of subjects enrolled	United States: 483
Country: Number of subjects enrolled	Germany: 30
Worldwide total number of subjects	829
EEA total number of subjects	220

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	485
From 65 to 84 years	334
85 years and over	10

Subject disposition

Recruitment

Recruitment details:

This was a long-term follow-up study that enrolled patients after participation in the preceding studies 191622-095 (NCT00910845) and 191622-520 (NCT00910520). A total of 829 patients received at least 1 BOTOX treatment in Study 191622-096 or in the preceding studies.

Pre-assignment

Screening details:

Following a planned interim analysis, the protocol was amended to remove the option to escalate to the 150U dose. The dose groups reflect the highest dose received (i.e. 100U BOTOX includes patients who only received 100U throughout the study and 150U BOTOX includes patients who received at least 1 dose of 150U at any time during the study).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	botulinum toxin Type A 100U

Arm description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

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 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Arm title	botulinum toxin Type A 150U

Arm description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

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 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Number of subjects in period 1	botulinum toxin Type A 100U	botulinum toxin Type A 150U
Started	543	286
Completed	278	151
Not completed	265	135
Retreat Request >Wk 144 (exclusionary)	4	5
Patient Moved	15	9
Other Reason	35	12
Study Burden	28	12
Missing	12	1
Consent withdrawn by subject	59	21
Non-Compliance	3	1
Site Closed	27	9
Adverse event, non-fatal	29	13
Pregnancy	2	-
Lost to follow-up	27	16
Protocol deviation	9	4
Lack of efficacy	15	32

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	829	829	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	60.1		
standard deviation	± 13.37	-	
Gender, Male/Female Units: Participants			
Female	749	749	
Male	80	80	

Subject analysis sets	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 1
Subject analysis set type	Sub-group analysis
Subject analysis set description: all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 2
Subject analysis set type	Sub-group analysis
Subject analysis set description: all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 2
Subject analysis set type	Sub-group analysis
Subject analysis set description: all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 3
Subject analysis set type	Sub-group analysis
Subject analysis set description: all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 3
Subject analysis set type	Sub-group analysis
Subject analysis set description: all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 4
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 5
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 5
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 6
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 6
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Reporting group values	botulinum toxin Type A 100U Treatment Cycle 1	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2
Number of subjects	829	608	116
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	60.15	60.35	59.24
standard deviation	± 13.37	± 13.03	± 14.5
Gender, Male/Female			
Units: Participants			
Female	749	553	101
Male	80	55	15

Reporting group values	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3	botulinum toxin Type A 100U Treatment Cycle 4
Number of subjects	388	179	273
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	60.76	58	59.74

standard deviation	± 13.17	± 14.18	± 13.64

Gender, Male/Female Units: Participants			
Female	362	164	257
Male	26	15	16

Reporting group values	botulinum toxin Type A 150U Treatment Cycle 4	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5
Number of subjects	131	185	88
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	58.73	59.45	60.76
standard deviation	± 13.03	± 12.28	± 12.24
Gender, Male/Female Units: Participants			
Female	123	172	83
Male	8	13	5

Reporting group values	botulinum toxin Type A 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6	
Number of subjects	139	50	
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	59.58	60.08	
standard deviation	± 11.13	± 12.83	
Gender, Male/Female Units: Participants			
Female	132	49	
Male	7	1	

End points

End points reporting groups

Reporting group title	botulinum toxin Type A 100U
Reporting group description:	
Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.	
Reporting group title	botulinum toxin Type A 150U
Reporting group description:	
Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 1
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 2
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 3
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 3
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 4
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 5
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)	
Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 5
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Subject analysis set title	botulinum toxin Type A 100U Treatment Cycle 6
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 100 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

Subject analysis set title	botulinum toxin Type A 150U Treatment Cycle 6
Subject analysis set type	Sub-group analysis

Subject analysis set description:

all patients with data at the time point who received at least 1 BOTOX 150 U treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520)

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[1]

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 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in incontinence episodes (improvement) and a positive number change from baseline indicates an increase in the number of incontinence episodes (worsening).

End point type	Primary

End point timeframe:

Study Baseline, Week 12 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 100U Treatment Cycle 1			
Subject group type	Subject analysis set			
Number of subjects analysed	829			
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	5.55 (± 3.617)			
Chg from Study BL at Wk 12 Tmt Cycle1 (N=812)	-3.26 (± 3.439)			

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[2]

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 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in incontinence episodes (improvement) and a positive number change from baseline indicates an increase in the number of incontinence episodes (worsening).

End point type	Primary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 2

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 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	608	116		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	5.7 (± 3.685)	5.66 (± 3.798)		
Chg from Study BL at Wk 12 Tmt Cycle2 (N=597, 108)	-3.64 (± 3.402)	-3.05 (± 3.69)		

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[3]

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 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in incontinence episodes (improvement) and a positive number change from baseline indicates an increase in the number of incontinence episodes (worsening).

End point type	Primary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 3

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 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	388	179		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	5.65 (± 3.38)	6.3 (± 4.28)		
Chg from Study BL at Wk 12 Tmt Cycle3 (N=372, 170)	-3.82 (± 3.341)	-3.46 (± 3.771)		

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[4]

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 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in incontinence episodes (improvement) and a positive number change from baseline indicates an increase in the number of incontinence episodes (worsening).

End point type	Primary

End point timeframe:

Study Baseline, Week 12 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 100U Treatment Cycle 4	botulinum toxin Type A 150U Treatment Cycle 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	273	131		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	5.78 (± 3.463)	6.19 (± 4.14)		
Chg from Study BL at Wk 12 Tmt Cycle4 (N=264, 122)	-3.48 (± 3.733)	-3.32 (± 3.972)		

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[5]

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 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in incontinence episodes (improvement) and a positive number change from baseline indicates an increase in the number of incontinence episodes (worsening).

End point type	Primary

End point timeframe:

Study Baseline, Week 12 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 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185	88		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	5.47 (± 3.283)	6.43 (± 3.622)		
Chg from Study BL at Wk 12 Tmt Cycle5 (N=181, 85)	-3.34 (± 3.791)	-3.58 (± 3.266)		

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[6]

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 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of incontinence episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in incontinence episodes (improvement) and a positive number change from baseline indicates an increase in the number of incontinence episodes (worsening).

End point type	Primary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 6

Notes:

[6] - 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 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	139	50		
Units: Incontinence Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	5.65 (± 3.238)	7.17 (± 4.223)		
Chg from Study BL at Wk 12 Tmt Cycle6 (N=136, 48)	-3.05 (± 3.493)	-3.12 (± 3.753)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Patients with a Positive Response on the 4-Point Treatment Benefit Scale (TBS)

End point title	Percentage of Patients with a Positive Response on the 4-Point Treatment Benefit Scale (TBS)[7]

End point description:

The TBS is a single-item scale in which the patient considers his/her current condition (urinary problems, urinary incontinence) compared with his/her condition before receiving any study treatment in study 191622-095 or 191622-520. Response options are: 1 = greatly improved; 2 = improved; 3 = not changed; and 4 = worsened. Patients scoring either "greatly improved" or "improved" are considered to have a positive response.

End point type	Primary

End point timeframe:

Week 12 Treatment Cycle 1

Notes:

[7] - 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 100U Treatment Cycle 1			
Subject group type	Subject analysis set			
Number of subjects analysed	812			
Units: Percentage of Patients				
number (not applicable)	74			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Patients with a Positive Response on the 4-Point TBS

End point title	Percentage of Patients with a Positive Response on the 4-Point TBS[8]

End point description:

The TBS is a single-item scale in which the patient considers his/her current condition (urinary problems, urinary incontinence) compared with his/her condition before receiving any study treatment in study 191622-095 or 191622-520. Response options are: 1 = greatly improved; 2 = improved; 3 = not changed; and 4 = worsened. Patients scoring either "greatly improved" or "improved" are considered to have a positive response.

End point type	Primary

End point timeframe:

Week 12 Treatment Cycle 2

Notes:

[8] - 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 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	594	110		
Units: Percentage of Patients				
number (not applicable)	81.3	71.8		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Patients with a Positive Response on the 4-Point TBS

End point title	Percentage of Patients with a Positive Response on the 4-Point TBS[9]

End point description:

The TBS is a single-item scale in which the patient considers his/her current condition (urinary problems, urinary incontinence) compared with his/her condition before receiving any study treatment in study 191622-095 or 191622-520. Response options are: 1 = greatly improved; 2 = improved; 3 = not changed; and 4 = worsened. Patients scoring either "greatly improved" or "improved" are considered to have a positive response.

End point type	Primary

End point timeframe:

Week 12 Treatment Cycle 3

Notes:

[9] - 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 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	374	173		
Units: Percentage of Patients				
number (not applicable)	82.1	71.1		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Patients with a Positive Response on the 4-Point TBS

End point title	Percentage of Patients with a Positive Response on the 4-Point TBS[10]

End point description:

The TBS is a single-item scale in which the patient considers his/her current condition (urinary problems, urinary incontinence) compared with his/her condition before receiving any study treatment in study 191622-095 or 191622-520. Response options are: 1 = greatly improved; 2 = improved; 3 = not changed; and 4 = worsened. Patients scoring either "greatly improved" or "improved" are considered to have a positive response.

End point type	Primary

End point timeframe:

Week 12 Treatment Cycle 4

Notes:

[10] - 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 100U Treatment Cycle 4	botulinum toxin Type A 150U Treatment Cycle 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	263	123		
Units: Percentage of Patients				
number (not applicable)	78.3	81.3		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Patients with a Positive Response on the 4-Point TBS

End point title	Percentage of Patients with a Positive Response on the 4-Point TBS[11]

End point description:

The TBS is a single-item scale in which the patient considers his/her current condition (urinary problems, urinary incontinence) compared with his/her condition before receiving any study treatment in study 191622-095 or 191622-520. Response options are: 1 = greatly improved; 2 = improved; 3 =

not changed; and 4 = worsened. Patients scoring either "greatly improved" or "improved" are considered to have a positive response.

End point type	Primary

End point timeframe:

Week 12 Treatment Cycle 5

Notes:

[11] - 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 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	179	86		
Units: Percentage of Patients				
number (not applicable)	83.2	81.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Patients with a Positive Response on the 4-Point TBS

End point title	Percentage of Patients with a Positive Response on the 4-Point TBS[12]

End point description:

The TBS is a single-item scale in which the patient considers his/her current condition (urinary problems, urinary incontinence) compared with his/her condition before receiving any study treatment in study 191622-095 or 191622-520. Response options are: 1 = greatly improved; 2 = improved; 3 = not changed; and 4 = worsened. Patients scoring either "greatly improved" or "improved" are considered to have a positive response.

End point type	Primary

End point timeframe:

Week 12 Treatment Cycle 6

Notes:

[12] - 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 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	136	48		
Units: Percentage of Patients				
number (not applicable)	80.9	81.3		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point title	Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point description:

The number of micturition (urination) episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of micturition episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in micturition episodes (improvement) and a positive number change from baseline indicates an increase in the number of micturition episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 1

End point values	botulinum toxin Type A 100U Treatment Cycle 1			
Subject group type	Subject analysis set			
Number of subjects analysed	829			
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	11.7 (± 3.584)			
Chg from Study BL at Wk 12 Tmt Cycle1 (N=812)	-2.6 (± 2.887)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point title	Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point description:

The number of micturition (urination) episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of micturition episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in micturition episodes (improvement) and a positive number change from baseline indicates an increase in the number of micturition episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 2

End point values	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	608	116		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	11.83 (± 3.634)	11.48 (± 3.912)		
Chg from Study BL at Wk 12 Tmt Cycle2 (N=597, 108)	-2.89 (± 3.037)	-2.31 (± 3.293)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point title	Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point description:

The number of micturition (urination) episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of micturition episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in micturition episodes (improvement) and a positive number change from baseline indicates an increase in the number of micturition episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 3

End point values	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	388	179		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	11.65 (± 3.553)	12.22 (± 3.76)		
Chg from Study BL at Wk 12 Tmt Cycle3 (N=372, 170)	-2.86 (± 3.058)	-3.01 (± 3.217)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point title	Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point description:

The number of micturition (urination) episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of micturition episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in micturition episodes (improvement) and a positive number change from baseline indicates an increase in the number of micturition episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 4

End point values	botulinum toxin Type A 100U Treatment Cycle 4	botulinum toxin Type A 150U Treatment Cycle 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	273	131		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	11.68 (± 3.456)	11.82 (± 3.442)		
Chg from Study BL at Wk 12 Tmt Cycle4 (N=264, 122)	-2.69 (± 3.485)	-2.78 (± 2.882)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point title	Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point description:

The number of micturition (urination) episodes are recorded in a patient bladder diary in the 3

consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of micturition episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in micturition episodes (improvement) and a positive number change from baseline indicates an increase in the number of micturition episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 5

End point values	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185	88		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	11.55 (± 3.261)	11.79 (± 2.77)		
Chg from Study BL at Wk 12 Tmt Cycle5 (N=181, 85)	-2.85 (± 3.181)	-3.19 (± 2.772)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point title	Change from Study Baseline in the Daily Average Number of Micturition Episodes

End point description:

The number of micturition (urination) episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of micturition episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in micturition episodes (improvement) and a positive number change from baseline indicates an increase in the number of micturition episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 6

End point values	botulinum toxin Type A 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	139	50		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	11.85 (± 3.377)	11.81 (± 2.99)		
Chg from Study BL at Wk 12 Tmt Cycle6 (N=136, 48)	-2.76 (± 3.153)	-2.66 (± 3.351)		

Statistical analyses

No statistical analyses for this end point

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

End point title	Change from Study Baseline in the Urinary Incontinence-Specific Quality of Life (I-QOL) Questionnaire 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 191622-095 or 191622-520. Positive number changes from baseline indicate improved QOL and negative changes from baseline indicate worsened QOL.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 1

End point values	botulinum toxin Type A 100U Treatment Cycle 1			
Subject group type	Subject analysis set			
Number of subjects analysed	827			
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	34.3 (± 18.58)			
Chg from Study BL at Wk 12 Tmt Cycle1 (N=810)	26 (± 24.84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the I-QOL Questionnaire Total Summary Score

End point title	Change from Study Baseline in the I-QOL Questionnaire 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 191622-095 or 191622-520. Positive number changes from baseline indicate improved QOL and negative changes from baseline indicate worsened QOL

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 2

End point values	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	606	116		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	33.8 (± 18.72)	32.8 (± 17.91)		
Chg from Study BL at Wk 12 Tmt Cycle2 (N=586, 109)	28.6 (± 24.38)	21.6 (± 23.71)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the I-QOL Questionnaire Total Summary Score

End point title	Change from Study Baseline in the I-QOL Questionnaire 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 191622-095 or 191622-520. Positive number changes from baseline indicate improved QOL and negative changes from baseline indicate worsened QOL

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 3

End point values	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	386	179		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	33.8 (± 18.21)	31.9 (± 18.17)		
Chg from Study BL at Wk 12 Tmt Cycle3 (N=371, 173)	27.6 (± 22.39)	23.7 (± 25.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the I-QOL Questionnaire Total Summary Score

End point title	Change from Study Baseline in the I-QOL Questionnaire 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 191622-095 or 191622-520. Positive number changes from baseline indicate improved QOL and negative changes from baseline indicate worsened QOL

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 4

End point values	botulinum toxin Type A 100U Treatment Cycle 4	botulinum toxin Type A 150U Treatment Cycle 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	271	131		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	31.4 (± 17.32)	32.5 (± 19.36)		
Chg from Study BL at Wk 12 Tmt Cycle4 (N=261, 124)	27.3 (± 24.9)	20.3 (± 22.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the I-QOL Questionnaire Total Summary Score

End point title	Change from Study Baseline in the I-QOL Questionnaire 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 191622-095 or 191622-520. Positive number changes from baseline indicate improved QOL and negative changes from baseline indicate worsened QOL

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 5

End point values	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	184	88		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	31.2 (± 17.49)	31.9 (± 20.3)		
Chg from Study BL at Wk 12 Tmt Cycle5 (N=178, 86)	28.1 (± 23.75)	19.5 (± 21.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the I-QOL Questionnaire Total Summary Score

End point title	Change from Study Baseline in the I-QOL Questionnaire 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 191622-095 or 191622-520. Positive number changes from baseline indicate improved QOL and negative changes from baseline indicate worsened QOL

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 6

End point values	botulinum toxin Type A 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	138	50		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	30.3 (± 17.87)	30.2 (± 20.28)		
Chg from Study BL at Wk 12 Tmt Cycle5 (N=178, 86)	22.6 (± 24.99)	18.3 (± 14.91)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the King’s Health Questionnaire (KHQ) Role Limitations Domain

End point title	Change from Study Baseline in the King’s Health Questionnaire (KHQ) Role Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The role limitations domain consists of 2 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 1

End point values	botulinum toxin Type A 100U Treatment Cycle 1			
Subject group type	Subject analysis set			
Number of subjects analysed	824			
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	64.3 (± 28.77)			
Chg from Study BL at Wk 12 Tmt Cycle1 (N=813)	-28.5 (± 34.32)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Role Limitations Domain

End point title	Change from Study Baseline in the KHQ Role Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The role limitations domain consists of 2 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 2

End point values	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	605	115		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	64.5 (± 28.51)	66.2 (± 30.15)		
Chg from Study BL at Wk 12 Tmt Cycle2 (N=585, 109)	-32.1 (± 34.29)	-29.2 (± 35.94)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Role Limitations Domain

End point title	Change from Study Baseline in the KHQ Role Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The role limitations domain consists of 2 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 3

End point values	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	387	177		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	64.7 (± 28.36)	63.4 (± 30.41)		
Chg from Study BL at Wk 12 Tmt Cycle3 (N=373, 171)	-29.7 (± 33.47)	-27.9 (± 34.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Role Limitations Domain

End point title	Change from Study Baseline in the KHQ Role Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The role limitations domain consists of 2 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 4

End point values	botulinum toxin Type A 100U Treatment Cycle 4	botulinum toxin Type A 150U Treatment Cycle 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	272	130		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	66.3 (± 27.65)	62.3 (± 31.17)		
Chg from Study BL at Wk 12 Tmt Cycle4 (N=261, 123)	-30.9 (± 33.82)	-23.4 (± 33.05)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Role Limitations Domain

End point title	Change from Study Baseline in the KHQ Role Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The role limitations domain consists of 2 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 5

End point values	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185	87		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	65.4 (± 29.15)	62.6 (± 31.84)		
Chg from Study BL at Wk 12 Tmt Cycle5 (N=179, 85)	-30.8 (± 35.13)	-26.3 (± 28.45)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Role Limitations Domain

End point title	Change from Study Baseline in the KHQ Role Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The role limitations domain consists of 2 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 6

End point values	botulinum toxin Type A 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	138	50		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	66.4 (± 30)	60.3 (± 33.15)		
Chg from Study BL at Wk 12 Tmt Cycle6 (N=134, 48)	-24.8 (± 38.93)	-22.9 (± 25.64)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Social Limitations Domain

End point title	Change from Study Baseline in the KHQ Social Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The social limitations domain consists of 4 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 1

End point values	botulinum toxin Type A 100U Treatment Cycle 1			
Subject group type	Subject analysis set			
Number of subjects analysed	824			
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	43.1 (± 30.79)			
Chg from Study BL at Wk 12 Tmt Cycle1 (N=813)	-18.4 (± 29.46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Social Limitations Domain

End point title	Change from Study Baseline in the KHQ Social Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The social limitations domain consists of 4 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 2

End point values	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	605	115		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	43 (± 30.96)	48.4 (± 30.12)		
Chg from Study BL at Wk 12 Tmt Cycle2 (N=585, 109)	-20 (± 29.12)	-19 (± 28.55)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Social Limitations Domain

End point title	Change from Study Baseline in the KHQ Social Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The social limitations domain consists of 4 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 3

End point values	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	387	177		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	42.8 (± 31.02)	45.4 (± 31.38)		
Chg from Study BL at Wk 12 Tmt Cycle3 (N=373, 171)	-17.9 (± 29.26)	-19.2 (± 28.31)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Social Limitations Domain

End point title	Change from Study Baseline in the KHQ Social Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The social limitations domain consists of 4 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 4

End point values	botulinum toxin Type A 100U Treatment Cycle 4	botulinum toxin Type A 150U Treatment Cycle 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	272	130		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	44.7 (± 31.86)	43.2 (± 30.46)		
Chg from Study BL at Wk 12 Tmt Cycle4 (N=261, 123)	-19.8 (± 31.26)	-16.1 (± 23.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Social Limitations Domain

End point title	Change from Study Baseline in the KHQ Social Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The social limitations domain consists of 4 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 5

End point values	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185	87		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	44.4 (± 31.39)	43.4 (± 32.89)		
Chg from Study BL at Wk 12 Tmt Cycle5 (N=179, 85)	-21.7 (± 28.47)	-15.7 (± 24.52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Study Baseline in the KHQ Social Limitations Domain

End point title	Change from Study Baseline in the KHQ Social Limitations Domain

End point description:

The KHQ is a disease-specific health-related QOL questionnaire that measures urinary incontinence. The social limitations domain consists of 4 questions answered on a 4-point scale (not at all, slightly, moderate, a lot). The initial study baseline is obtained from data collected prior to the first treatment in Study 191622-095 or 191622-520. Positive number changes from baseline indicate a worsening in role limitations and negative number changes from baseline indicate an improvement in role limitations.

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 6

End point values	botulinum toxin Type A 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	138	50		
Units: Scores on a Scale				
arithmetic mean (standard deviation)				
Study Baseline (BL)	46.7 (± 32.72)	43.3 (± 32.56)		
Chg from Study BL at Wk 12 Tmt Cycle6 (N=134, 48)	-17 (± 33.59)	-17.6 (± 24.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Study Baseline in Daily Frequency of Urgency Episodes

End point title	Change From Study Baseline in Daily Frequency of Urgency Episodes

End point description:

The number of urgency episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of urgency episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in urgency episodes (improvement) and a positive number change from baseline indicates an increase in the number of urgency episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 1

End point values	botulinum toxin Type A 100U Treatment Cycle 1			
Subject group type	Subject analysis set			
Number of subjects analysed	829			
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	8.55 (± 4.206)			
Chg from Study BL at Wk 12 Tmt Cycle1 (N=812)	-3.81 (± 4.031)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Study Baseline in Daily Frequency of Urgency Episodes

End point title	Change From Study Baseline in Daily Frequency of Urgency Episodes

End point description:

The number of urgency episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of urgency episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in urgency episodes (improvement) and a positive number change from baseline indicates an increase in the number of urgency episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 2

End point values	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	608	116		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	8.63 (± 4.188)	9.09 (± 4.764)		
Chg from Study BL at Wk 12 Tmt Cycle2 (N=597, 108)	-4.07 (± 4.046)	-3.96 (± 4.519)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Study Baseline in Daily Frequency of Urgency Episodes

End point title	Change From Study Baseline in Daily Frequency of Urgency Episodes

End point description:

The number of urgency episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of urgency episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in urgency episodes (improvement) and a positive number change from baseline indicates an increase in the number of urgency episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 3

End point values	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	388	179		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	8.62 (± 4.055)	9.28 (± 4.552)		
Chg from Study BL at Wk 12 Tmt Cycle3 (N=372, 170)	-4.22 (± 4.12)	-3.86 (± 4.332)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Study Baseline in Daily Frequency of Urgency Episodes

End point title	Change From Study Baseline in Daily Frequency of Urgency Episodes

End point description:

The number of urgency episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of urgency episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in urgency episodes (improvement) and a positive number change from baseline indicates an increase in the number of urgency episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 4

End point values	botulinum toxin Type A 100U Treatment Cycle 4	botulinum toxin Type A 150U Treatment Cycle 4		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	273	131		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	8.65 (± 3.951)	8.98 (± 4.241)		
Chg from Study BL at Wk 12 Tmt Cycle4 (N=264, 122)	-3.92 (± 4.341)	-3.5 (± 3.916)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Study Baseline in Daily Frequency of Urgency Episodes

End point title	Change From Study Baseline in Daily Frequency of Urgency Episodes

End point description:

The number of urgency episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of urgency episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in urgency episodes (improvement) and a positive number change from baseline indicates an increase in the number of urgency episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 5

End point values	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185	88		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	8.67 (± 3.961)	8.89 (± 3.341)		
Chg from Study BL at Wk 12 Tmt Cycle5 (N=181, 85)	-4.11 (± 4.549)	-3.56 (± 3.576)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Study Baseline in Daily Frequency of Urgency Episodes

End point title	Change From Study Baseline in Daily Frequency of Urgency Episodes

End point description:

The number of urgency episodes are recorded in a patient bladder diary in the 3 consecutive days prior to each study visit for study 191622-096 (or 3 days prior to each visit in study 191622-095 or 191622-520). The number of urgency episodes are averaged daily during this period. The initial study baseline is obtained from the patient bladder diary in the 3 consecutive days prior to the first treatment in either study 191622-095 or 191622-520. A negative number change from baseline indicates a reduction in urgency episodes (improvement) and a positive number change from baseline indicates an increase in the number of urgency episodes (worsening).

End point type	Secondary

End point timeframe:

Study Baseline, Week 12 Treatment Cycle 6

End point values	botulinum toxin Type A 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	139	50		
Units: Number of Episodes				
arithmetic mean (standard deviation)				
Study Baseline (BL)	8.98 (± 4.059)	8.84 (± 3.629)		
Chg from Study BL at Wk 12 Tmt Cycle6 (N=136, 48)	-3.95 (± 4.662)	-2.64 (± 4.112)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Adverse events were monitored from informed consent signature to the end of study for each subject.

Adverse event reporting additional description:

BOTOX-Treated Population includes all patients who received at least 1 BOTOX treatment since the start of their clinical study participation (in study 191622-096, 191622-095 or 191622-520), 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	17.0

Reporting groups

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 1

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 2

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 2

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 3

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 3

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 4

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 4

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 5

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 5

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 6

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no

more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 6

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 7

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 7

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 8

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 8

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 9

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 9

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 10

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 150U Treatment Cycle 10

Reporting group description:

Botulinum toxin Type A 150U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 11

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 12

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Reporting group title	botulinum toxin Type A 100U Treatment Cycle 13

Reporting group description:

Botulinum toxin Type A 100U injected into the detrusor, after protocol specified criteria are met, and no more frequently than every 12 weeks.

Serious adverse events	botulinum toxin Type A 100U Treatment Cycle 1	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2
Total subjects affected by serious adverse events			
subjects affected / exposed	71 / 829 (8.56%)	62 / 608 (10.20%)	7 / 116 (6.03%)
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 / 829 (0.12%)	5 / 608 (0.82%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Stage II			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Invasive Ductal Breast Carcinoma			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Lung Carcinoma Cell Type Unspecified Stage III			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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: MALE ONLY		
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Squamous Cell Carcinoma			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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: FEMALE ONLY		

subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Benign Neoplasm of Spinal Cord			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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 Cancer			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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 Adenoma			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Bladder Cancer			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyogenic Granuloma			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Ovarian Tumour	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			

subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Arterial Thrombosis			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Hypotension			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			

subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Deep Vein Thrombosis			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Thrombosis			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Arterial Disorder			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal Arteritis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Preventive Surgery			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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			

Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Hernia Obstructive			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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 Device Complication			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Ineffective			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			

Drug Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to Plants			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Shock			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Benign Prostatic Hyperplasia	Additional description: MALE ONLY		
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Polycystic Ovaries	Additional description: FEMALE ONLY		
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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 Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Cervical Polyp	Additional description: FEMALE ONLY		

subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Uterine Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Hypertrophy	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Pulmonary Embolism			
subjects affected / exposed	3 / 829 (0.36%)	3 / 608 (0.49%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 829 (0.24%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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 Respiratory Failure			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal obstruction			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Major Depression			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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

Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Depression Suicidal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Suicide Attempt			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
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			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Sigmoidoscopy			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Aspartate Aminotransferase			

Increased			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Increased			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Comminuted Fracture			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Femur Fracture			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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 Fracture			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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			

subjects affected / exposed	0 / 829 (0.00%)	2 / 608 (0.33%)	0 / 116 (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
Lower Limb Fracture			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Patella Fracture			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Procedural Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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 Fracture			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Tibia Fracture			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Wound			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Humerus Fracture			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Accidental Overdose			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Dehiscence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Limb Fracture			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation Injury			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Congenital Diaphragmatic Hernia			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Supraventricular Tachycardia			
subjects affected / exposed	2 / 829 (0.24%)	0 / 608 (0.00%)	0 / 116 (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
Angina Pectoris			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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	1 / 829 (0.12%)	2 / 608 (0.33%)	0 / 116 (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
Cardiac Failure Congestive			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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

Coronary Artery Disease			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Myocardial Infarction			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Palpitations			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Ventricular Tachycardia			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Arrhythmia			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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 Unstable			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Cardiomyopathy			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Arrest			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Bulbar Palsy			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Carpal Tunnel Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Cerebral Infarction			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Cerebrovascular Disorder			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Hemiparesis			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Migraine			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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

Obturator Neuropathy			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Restless Legs Syndrome			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Syncope			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Haemorrhage Intracranial			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Artery Thrombosis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Radiculopathy			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peroneal Nerve Palsy			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Anaemia			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Iron Deficiency Anaemia			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Coagulopathy			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Cataract			

subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Vitreous Floaters			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Abdominal Pain Lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Colitis			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Crohn’s Disease			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Inguinal Hernia			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Pancreatitis			

subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Volvulus			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Small Intestinal Obstruction			
subjects affected / exposed	0 / 829 (0.00%)	3 / 608 (0.49%)	0 / 116 (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
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Internal Hernia			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large Intestine Polyp			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			

subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Cholecystitis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Actinic keratosis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Ulcer			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Renal Failure Acute			
subjects affected / exposed	2 / 829 (0.24%)	0 / 608 (0.00%)	0 / 116 (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
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 829 (0.24%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Ureteric			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urge Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Haematuria			

subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Cystitis Interstitial			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Goitre			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Osteoarthritis			
alternative assessment type: Non-systematic			

subjects affected / exposed	7 / 829 (0.84%)	8 / 608 (1.32%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 10	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 829 (0.24%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 829 (0.24%)	0 / 608 (0.00%)	0 / 116 (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
Spinal Column Stenosis			
subjects affected / exposed	2 / 829 (0.24%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 3	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 / 829 (0.12%)	2 / 608 (0.33%)	0 / 116 (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
Intervertebral Disc Protrusion			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (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
Muscle Spasms			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Pain in Extremity			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 829 (0.00%)	2 / 608 (0.33%)	0 / 116 (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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 Disorder			

subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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			
Pneumonia			
subjects affected / exposed	3 / 829 (0.36%)	2 / 608 (0.33%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	2 / 829 (0.24%)	0 / 608 (0.00%)	0 / 116 (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
Cellulitis			
subjects affected / exposed	2 / 829 (0.24%)	2 / 608 (0.33%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal Abscess			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Diverticulitis			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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			
subjects affected / exposed	0 / 829 (0.00%)	3 / 608 (0.49%)	0 / 116 (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
Localised infection			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Lung Infection			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Sinusitis			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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
Infected Skin Ulcer			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	1 / 116 (0.86%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			

subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
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	2 / 829 (0.24%)	0 / 608 (0.00%)	0 / 116 (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
Diabetes Mellitus			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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

Hyperglycaemia			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Acidosis			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (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
Dehydration			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (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

Serious adverse events	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3	botulinum toxin Type A 100U Treatment Cycle 4
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 388 (8.25%)	13 / 179 (7.26%)	18 / 273 (6.59%)
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 / 388 (0.26%)	1 / 179 (0.56%)	0 / 273 (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
Breast Cancer Stage II			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Carcinoma Cell Type Unspecified Stage III			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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: MALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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	2 / 388 (0.52%)	0 / 179 (0.00%)	0 / 273 (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
Uterine Leiomyoma	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Spinal Cord			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Adenoma			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyogenic Granuloma			

subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Benign Ovarian Tumour	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Malignant Melanoma			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
B-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Arterial Thrombosis			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Disorder			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Temporal Arteritis			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Varicose Vein			

subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Hypertensive Crisis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Preventive Surgery			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia Obstructive			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Device Complication			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Device Ineffective			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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			
Drug Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to Plants			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Anaphylactic Shock			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia	Additional description: MALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycystic Ovaries	Additional description: FEMALE ONLY		

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Polyp	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Perineal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Endometrial Hypertrophy	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			

Pulmonary Embolism			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Respiratory Failure			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Nasal obstruction			

subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Emphysema			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Psychiatric disorders			
Major Depression			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Suicidal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Mental Status Changes			

subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Sigmoidoscopy			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate Aminotransferase Increased			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Heart Rate Increased			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Comminuted Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Femur Fracture			

subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Overdose			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Incisional Hernia			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Rib Fracture			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Ankle Fracture			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Dehiscence			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Procedural Haemorrhage			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Limb Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation Injury			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital Diaphragmatic Hernia			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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			
Supraventricular Tachycardia			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Atrial Fibrillation			
subjects affected / exposed	2 / 388 (0.52%)	0 / 179 (0.00%)	0 / 273 (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
Cardiac Failure Congestive			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Tachycardia			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Unstable			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Stress Cardiomyopathy			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Mitral Valve Prolapse			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Arrest			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Bulbar Palsy			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cerebral Infarction			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obturator Neuropathy			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless Legs Syndrome			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Carotid Artery Stenosis			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Cerebral Artery Thrombosis			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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 Radiculopathy			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Parkinsonism			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Peroneal Nerve Palsy			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Transient Ischaemic Attack			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Anaemia			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Ear and labyrinth disorders			
Vertigo			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Cataract			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Vitreous Floaters			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn’s Disease			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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 Haemorrhage			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal Hernia			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 Polyp			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Dermatitis Atopic			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Actinic keratosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Ulcer			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Renal Failure Acute			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Calculus Ureteric			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Urge Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis Interstitial			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Hydroureter			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Pelvi-Ureteric Obstruction			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Glomerulonephritis			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Goitre			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 388 (0.52%)	0 / 179 (0.00%)	0 / 273 (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
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Arthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Spinal Column Stenosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Spasms			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	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	1 / 388 (0.26%)	1 / 179 (0.56%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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 Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	2 / 273 (0.73%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon Disorder			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
Pneumonia			
subjects affected / exposed	3 / 388 (0.77%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal Abscess			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diverticulitis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
subjects affected / exposed	2 / 388 (0.52%)	0 / 179 (0.00%)	0 / 273 (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
Localised infection			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Skin Ulcer			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.26%)	2 / 179 (1.12%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Cystitis			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Staphylococcal Infection			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (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
Sepsis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (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
Diabetes Mellitus			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Acidosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
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 150U Treatment Cycle 4	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 131 (6.11%)	15 / 185 (8.11%)	4 / 88 (4.55%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Stage II			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Carcinoma Cell Type Unspecified Stage III			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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: MALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Spinal Cord			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Adenoma			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyogenic Granuloma			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Ovarian Tumour	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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
Squamous Cell Carcinoma of Skin			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Arterial Thrombosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Thrombosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Disorder			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal Arteritis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Preventive Surgery			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Chest Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia Obstructive			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Device Complication			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Ineffective			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Drug Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to Plants			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Shock			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Benign Prostatic Hyperplasia	Additional description: MALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycystic Ovaries	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Polyp	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal pain			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Hypertrophy	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary Embolism			
subjects affected / exposed	0 / 131 (0.00%)	2 / 185 (1.08%)	0 / 88 (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
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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 Failure			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Respiratory Failure			

subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Hypoxia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal obstruction			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Major Depression			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Suicidal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Investigations			
Sigmoidoscopy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Increased			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Injury, poisoning and procedural complications			
Comminuted Fracture			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Overdose			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Dehiscence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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
Forearm Fracture			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Upper Limb Fracture			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Radiation Injury			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital Diaphragmatic Hernia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Supraventricular Tachycardia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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 Failure Congestive			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Tachycardia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Unstable			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Cardiomyopathy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Cardiac Arrest			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Bulbar Palsy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Infarction			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obturator Neuropathy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless Legs Syndrome			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Artery Thrombosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Radiculopathy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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			
Anaemia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Eye disorders			
Cataract			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Floaters			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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
Gastrointestinal disorders			
Abdominal Pain			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	2 / 131 (1.53%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal Pain Lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn’s Disease			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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

Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal Hernia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Polyp			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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
Enterovesical Fistula			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Haematemesis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Actinic keratosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Ulcer			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			

Renal Failure Acute			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Ureteric			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urge Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis Interstitial			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Goitre			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	1 / 88 (1.14%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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
Arthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	2 / 185 (1.08%)	0 / 88 (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
Spinal Column Stenosis			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (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	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Spasms			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Osteoarthritis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 131 (0.00%)	2 / 185 (1.08%)	0 / 88 (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
Appendicitis			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (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
Appendiceal Abscess			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Skin Ulcer			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Acidosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
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 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6	botulinum toxin Type A 100U Treatment Cycle 7
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 139 (5.76%)	3 / 50 (6.00%)	3 / 93 (3.23%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Stage II			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Carcinoma Cell Type Unspecified Stage III			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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: MALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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	2 / 139 (1.44%)	1 / 50 (2.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma	Additional description: FEMALE ONLY		

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Spinal Cord			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Adenoma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyogenic Granuloma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Ovarian Tumour	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Arterial Thrombosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Disorder			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal Arteritis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Preventive Surgery			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			

Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia Obstructive			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Device Complication			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Ineffective			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			

Drug Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to Plants			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Shock			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Benign Prostatic Hyperplasia	Additional description: MALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycystic Ovaries	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Polyp	Additional description: FEMALE ONLY		

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Hypertrophy	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Pulmonary Embolism			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Respiratory Failure			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal obstruction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Major Depression			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Suicidal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Sigmoidoscopy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate Aminotransferase			

Increased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Increased			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Comminuted Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Accidental Overdose			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Dehiscence			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (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			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Limb Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation Injury			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital Diaphragmatic Hernia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Supraventricular Tachycardia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Failure Congestive			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Coronary Artery Disease			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Tachycardia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Unstable			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Cardiomyopathy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Arrest			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Bulbar Palsy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Infarction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Obturator Neuropathy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless Legs Syndrome			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Artery Thrombosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Radiculopathy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Peroneal Nerve Palsy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Anaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Cataract			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Floaters			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn’s Disease			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (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
Volvulus			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	1 / 50 (2.00%)	0 / 93 (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
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal Hernia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Polyp			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Actinic keratosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Ulcer			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Renal Failure Acute			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Ureteric			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (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
Urge Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis Interstitial			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (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
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Osteoarthritis			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (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
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Column Stenosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Spasms			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 Disorder			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 139 (0.00%)	1 / 50 (2.00%)	0 / 93 (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
Appendicitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal Abscess			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (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
Localised infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Skin Ulcer			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 / 139 (0.00%)	1 / 50 (2.00%)	0 / 93 (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
Arthritis Bacterial			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (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 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperglycaemia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Acidosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
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 150U Treatment Cycle 7	botulinum toxin Type A 100U Treatment Cycle 8	botulinum toxin Type A 150U Treatment Cycle 8
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 27 (0.00%)	4 / 69 (5.80%)	0 / 11 (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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Stage II			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Carcinoma Cell Type Unspecified Stage III			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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: MALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Spinal Cord			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Adenoma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyogenic Granuloma			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Ovarian Tumour	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	0 / 11 (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
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	1 / 69 (1.45%)	0 / 11 (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			
Arterial Thrombosis			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Disorder			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal Arteritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Preventive Surgery			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia Obstructive			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Device Complication			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Ineffective			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Drug Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to Plants			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Shock			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Benign Prostatic Hyperplasia	Additional description: MALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycystic Ovaries	Additional description: FEMALE ONLY		

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Polyp	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Hypertrophy	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			

Pulmonary Embolism			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Respiratory Failure			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal obstruction			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Major Depression			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Suicidal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Sigmoidoscopy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Increased			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Comminuted Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella Fracture			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	0 / 11 (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
Procedural Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Overdose			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Dehiscence			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Limb Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation Injury			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital Diaphragmatic Hernia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Supraventricular Tachycardia			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Failure Congestive			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Tachycardia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Unstable			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Cardiomyopathy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Arrest			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Bulbar Palsy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cerebral Infarction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obturator Neuropathy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless Legs Syndrome			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Carotid Artery Stenosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Artery Thrombosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Radiculopathy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Anaemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Cataract			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Floaters			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn’s Disease			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal Hernia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Polyp			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	0 / 11 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Dermatitis Atopic			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Actinic keratosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Ulcer			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Renal Failure Acute			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Retention			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Ureteric			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urge Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis Interstitial			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Goitre			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Column Stenosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Spasms			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	0 / 11 (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			
Pneumonia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal Abscess			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diverticulitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Skin Ulcer			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Acidosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
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 100U Treatment Cycle 9	botulinum toxin Type A 150U Treatment Cycle 9	botulinum toxin Type A 100U Treatment Cycle 10
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	1 / 37 (2.70%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Stage II			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Carcinoma Cell Type Unspecified Stage III			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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: MALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Spinal Cord			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Adenoma			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Cancer			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyogenic Granuloma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Ovarian Tumour	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Arterial Thrombosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Occlusive Disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial Disorder			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal Arteritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Crisis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Preventive Surgery			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hernia Obstructive			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Device Complication			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Ineffective			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Drug Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Allergy to Plants			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaphylactic Shock			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Benign Prostatic Hyperplasia	Additional description: MALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polycystic Ovaries	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Polyp	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Perineal pain			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Hypertrophy	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Pulmonary Embolism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Respiratory Failure			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal obstruction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Emphysema			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Major Depression			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Suicidal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental Status Changes			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Sigmoidoscopy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart Rate Increased			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Comminuted Fracture			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Patella Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural Pain			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accidental Overdose			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Dehiscence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Limb Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radiation Injury			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital Diaphragmatic Hernia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Supraventricular Tachycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Failure Congestive			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary Artery Disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular Tachycardia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Unstable			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Cardiomyopathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral Valve Prolapse			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Arrest			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Bulbar Palsy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal Tunnel Syndrome			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Infarction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparesis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obturator Neuropathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restless Legs Syndrome			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid Artery Stenosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Artery Thrombosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Radiculopathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peroneal Nerve Palsy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Anaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Cataract			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitreous Floaters			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn’s Disease			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Internal Hernia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Polyp			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterovesical Fistula			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Actinic keratosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Excessive skin			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Ulcer			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			

Renal Failure Acute			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Calculus Ureteric			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urge Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis Interstitial			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glomerulonephritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Goitre			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Column Stenosis			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot Deformity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Spasms			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Osteoarthritis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthropathy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 Disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendiceal Abscess			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung Infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected Skin Ulcer			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Sepsis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial Sepsis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal Infection			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis Bacterial			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes Mellitus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic Acidosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
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 150U Treatment Cycle 10	botulinum toxin Type A 100U Treatment Cycle 11	botulinum toxin Type A 100U Treatment Cycle 12
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	2 / 20 (10.00%)	1 / 5 (20.00%)
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 / 2 (0.00%)	0 / 20 (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 Stage II			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Lung Carcinoma Cell Type Unspecified Stage III			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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: MALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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: FEMALE ONLY		

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Benign Neoplasm of Spinal Cord			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Cancer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Adenoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Cancer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Pyogenic Granuloma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Benign Ovarian Tumour	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Lip Squamous Cell Carcinoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Malignant Melanoma			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Malignant Melanoma in Situ			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
B-Cell Small Lymphocytic Lymphoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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			
Arterial Thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Arterial Occlusive Disease			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Arterial Disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Temporal Arteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Varicose Vein			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Hypertensive Crisis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Preventive Surgery			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			

Fatigue			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Chest Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Hernia Obstructive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Device Complication			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Ineffective			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			

Drug Hypersensitivity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Allergy to Plants			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Anaphylactic Shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Benign Prostatic Hyperplasia	Additional description: MALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Polycystic Ovaries	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Polyp	Additional description: FEMALE ONLY		

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Perineal pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Endometrial Hypertrophy	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Pulmonary Embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Asthma			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Chronic Obstructive Pulmonary Disease			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Dyspnoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 Respiratory Failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Nasal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Emphysema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Major Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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

Anxiety			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Suicidal			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Suicide Attempt			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Mental Status Changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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			
Sigmoidoscopy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Aspartate Aminotransferase			

Increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Heart Rate Increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Comminuted Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	1 / 20 (5.00%)	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
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Patella Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Procedural Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Humerus Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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

Accidental Overdose			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Rib Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 Dehiscence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 Limb Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Radiation Injury			
subjects affected / exposed	1 / 2 (50.00%)	0 / 20 (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
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Congenital Diaphragmatic Hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Cardiac disorders			
Supraventricular Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Cardiac Failure Congestive			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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

Coronary Artery Disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Myocardial Infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Palpitations			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Ventricular Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 Unstable			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Cardiomyopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Mitral Valve Prolapse			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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

Cardiac Arrest			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	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
Nervous system disorders			
Bulbar Palsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Carpal Tunnel Syndrome			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Cerebral Infarction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Hemiparesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Migraine			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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

Obturator Neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Restless Legs Syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Haemorrhage Intracranial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Carotid Artery Stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Cerebral Artery Thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Radiculopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Parkinsonism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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

Peroneal Nerve Palsy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Transient Ischaemic Attack			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Iron Deficiency Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Coagulopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Ear and labyrinth disorders			
Vertigo			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Cataract			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Vitreous Floaters			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Abdominal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Lower			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Crohn’s Disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Inguinal Hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Pancreatitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 Haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Internal Hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Polyp			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Enterovesical Fistula			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Haematemesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Cholelithiasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	1 / 20 (5.00%)	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
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Actinic keratosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Excessive skin			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2 (50.00%)	0 / 20 (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
Renal and urinary disorders			
Renal Failure Acute			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Calculus Ureteric			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Urge Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Cystitis Interstitial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Pelvi-Ureteric Obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Glomerulonephritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Goitre			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Osteoarthritis			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Arthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Column Stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 Spasms			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Pain in Extremity			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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 Osteoarthritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Arthropathy			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 Disorder			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Osteonecrosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
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 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Appendiceal Abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Diverticulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Gastroenteritis Viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Lung Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Infected Skin Ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Staphylococcal Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Bacterial Sepsis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Cystitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Staphylococcal Infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 / 2 (0.00%)	0 / 20 (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
Arthritis Bacterial			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Gastroenteritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Metabolism and nutrition disorders			
Obesity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Diabetes Mellitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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

Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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
Metabolic Acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (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 100U Treatment Cycle 13		
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		
Breast Cancer Stage II			
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		
Lung Carcinoma Cell Type Unspecified Stage III			

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: MALE ONLY			
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			
Uterine Leiomyoma	Additional description: FEMALE ONLY			
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign Neoplasm of Spinal Cord				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal Cancer				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid Adenoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder Cancer				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyogenic Granuloma				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign Ovarian Tumour	Additional description: FEMALE ONLY			
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lip 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			
Malignant Melanoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant Melanoma in Situ				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
B-Cell Small Lymphocytic Lymphoma				
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 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			
Vascular disorders				
Arterial Thrombosis				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arterial Occlusive Disease				
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			
Thrombosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arterial Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Temporal Arteritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Varicose Vein				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive Crisis				
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				
Preventive Surgery				
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				
Fatigue				
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			
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			
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			
Hernia Obstructive				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical Device Complication				

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 Ineffective				
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				
Drug Hypersensitivity				
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			
Allergy to Plants				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaphylactic Shock				
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				
Benign Prostatic Hyperplasia	Additional description: MALE ONLY			
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Polycystic Ovaries	Additional description: FEMALE ONLY			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cervical Polyp	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine Prolapse	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal Haemorrhage	Additional description: FEMALE ONLY		
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Perineal 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		
Endometrial Hypertrophy	Additional description: FEMALE 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			

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			
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			
Chronic Obstructive Pulmonary Disease				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
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			
Acute 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			
Hypoxia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasal obstruction				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Emphysema				
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				
Major Depression				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				
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			
Depression Suicidal				
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			
Suicide Attempt				
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			
Depression				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mental Status Changes				

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				
Sigmoidoscopy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspartate Aminotransferase Increased				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Heart Rate Increased				
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				
Comminuted Fracture				
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			
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			
Lumbar Vertebral Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic 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				
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			
Patella Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural 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			
Stress 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			
Wound				
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			
Humerus Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Accidental Overdose				
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			
Rib Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Compression Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound Dehiscence				

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 Haemorrhage			
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		
Upper 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		
Radiation Injury			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Foramen Magnum Stenosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital Diaphragmatic Hernia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Supraventricular Tachycardia			

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				
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			
Cardiac Failure Congestive				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary Artery Disease				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
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			
Palpitations				
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			
Ventricular Tachycardia				
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			
Angina Unstable				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stress Cardiomyopathy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mitral Valve Prolapse				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Arrest				
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				
Bulbar Palsy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carpal Tunnel 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			
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			

Cerebral Infarction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hemiparesis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Obturator Neuropathy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Restless Legs Syndrome				
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			
Haemorrhage Intracranial				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Carotid Artery Stenosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral Artery Thrombosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical Radiculopathy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parkinsonism				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peroneal Nerve Palsy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient Ischaemic Attack				
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			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Iron Deficiency Anaemia				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coagulopathy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
Vertigo				
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			
Eye disorders				
Cataract				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vitreous Floaters				
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				
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			
Abdominal Pain Lower				
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			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Crohn’s Disease			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal Hernia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
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		
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		
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		
Internal Hernia			
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 Polyp			

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper 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			
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			
Enterovesical Fistula				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haematemesis				
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				
Cholelithiasis				
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				
Dermatitis Atopic				
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			
Swelling Face				
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			
Actinic keratosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Excessive skin				
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 Ulcer				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin Wrinkling				
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				
Renal Failure Acute				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
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			
Calculus Ureteric				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urge 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			
Haematuria				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis Interstitial				
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			
Pelvi-Ureteric Obstruction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Glomerulonephritis				

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			
Goitre			
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			
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		
Arthritis			
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		
Spinal Column Stenosis			
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			
Muscle Spasms				
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			
Pain in Extremity				
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			
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			
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			
Spinal 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			
Musculoskeletal 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			

Rotator Cuff Syndrome				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthropathy				
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 Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteonecrosis				
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				
Pneumonia				
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			
Appendiceal Abscess				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Diverticulitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Viral				
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				
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				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung Infection				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinusitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infected Skin Ulcer				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal Sepsis				
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		
Bacterial Sepsis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cystitis			
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		
Staphylococcal Infection			
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		
Arthritis Bacterial			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
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			
Diabetes Mellitus				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic Acidosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
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 100U Treatment Cycle 1	botulinum toxin Type A 100U Treatment Cycle 2	botulinum toxin Type A 150U Treatment Cycle 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	297 / 829 (35.83%)	204 / 608 (33.55%)	28 / 116 (24.14%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			

Capsular Contracture Associated with Breast Implant			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	8 / 829 (0.97%)	7 / 608 (1.15%)	0 / 116 (0.00%)
occurrences (all)	10	7	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	16 / 829 (1.93%)	20 / 608 (3.29%)	1 / 116 (0.86%)
occurrences (all)	18	21	1
Asthma			
subjects affected / exposed	5 / 829 (0.60%)	7 / 608 (1.15%)	0 / 116 (0.00%)
occurrences (all)	7	8	0
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	14 / 829 (1.69%)	9 / 608 (1.48%)	1 / 116 (0.86%)
occurrences (all)	22	9	1
Psychotic Disorder			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Investigations			
Residual Urine Volume			
subjects affected / exposed	26 / 829 (3.14%)	12 / 608 (1.97%)	0 / 116 (0.00%)
occurrences (all)	31	13	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	12 / 829 (1.45%)	6 / 608 (0.99%)	4 / 116 (3.45%)
occurrences (all)	15	8	4
Limb Injury			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	3 / 608 (0.49%)	0 / 116 (0.00%)
occurrences (all)	0	4	0
Femur Fracture			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 829 (0.48%)	2 / 608 (0.33%)	1 / 116 (0.86%)
occurrences (all)	4	2	1
Hand Fracture			
subjects affected / exposed	1 / 829 (0.12%)	2 / 608 (0.33%)	1 / 116 (0.86%)
occurrences (all)	1	2	1
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 829 (0.97%)	5 / 608 (0.82%)	0 / 116 (0.00%)
occurrences (all)	8	5	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 829 (0.36%)	4 / 608 (0.66%)	0 / 116 (0.00%)
occurrences (all)	3	4	0
Leukocytosis			
subjects affected / exposed	3 / 829 (0.36%)	3 / 608 (0.49%)	0 / 116 (0.00%)
occurrences (all)	3	3	0
Thrombocytopenia			
subjects affected / exposed	1 / 829 (0.12%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	8 / 829 (0.97%)	8 / 608 (1.32%)	0 / 116 (0.00%)
occurrences (all)	11	11	0
Eye Inflammation			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	23 / 829 (2.77%)	20 / 608 (3.29%)	2 / 116 (1.72%)
occurrences (all)	27	20	2
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 829 (0.97%)	8 / 608 (1.32%)	2 / 116 (1.72%)
occurrences (all)	9	8	2
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	13 / 829 (1.57%)	14 / 608 (2.30%)	0 / 116 (0.00%)
occurrences (all)	14	15	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 829 (0.24%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	3	0	0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences (all)	0	1	0
Skin Wrinkling			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 829 (0.48%)	3 / 608 (0.49%)	0 / 116 (0.00%)
occurrences (all)	4	3	0
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	71 / 829 (8.56%)	47 / 608 (7.73%)	7 / 116 (6.03%)
occurrences (all)	89	58	7
Cystitis Glandularis			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences (all)	1	1	0
Pollakiuria			
subjects affected / exposed	10 / 829 (1.21%)	13 / 608 (2.14%)	3 / 116 (2.59%)
occurrences (all)	14	17	5
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	34 / 829 (4.10%)	23 / 608 (3.78%)	0 / 116 (0.00%)
occurrences (all)	40	26	0
Haematuria			
subjects affected / exposed	25 / 829 (3.02%)	12 / 608 (1.97%)	2 / 116 (1.72%)
occurrences (all)	29	12	2
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 829 (0.48%)	4 / 608 (0.66%)	0 / 116 (0.00%)
occurrences (all)	6	5	0
Bladder Hypertrophy			
subjects affected / exposed	1 / 829 (0.12%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences (all)	1	1	0
Urine Abnormality			
subjects affected / exposed	2 / 829 (0.24%)	2 / 608 (0.33%)	1 / 116 (0.86%)
occurrences (all)	2	2	6
Musculoskeletal and connective tissue disorders			

Back Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	27 / 829 (3.26%)	26 / 608 (4.28%)	1 / 116 (0.86%)
occurrences (all)	32	28	1
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	16 / 829 (1.93%)	21 / 608 (3.45%)	1 / 116 (0.86%)
occurrences (all)	26	23	1
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	13 / 829 (1.57%)	16 / 608 (2.63%)	1 / 116 (0.86%)
occurrences (all)	15	20	1
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 829 (0.36%)	9 / 608 (1.48%)	0 / 116 (0.00%)
occurrences (all)	4	9	0
Tendonitis			
subjects affected / exposed	6 / 829 (0.72%)	3 / 608 (0.49%)	0 / 116 (0.00%)
occurrences (all)	9	0	4
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 829 (0.00%)	0 / 608 (0.00%)	0 / 116 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	225 / 829 (27.14%)	161 / 608 (26.48%)	17 / 116 (14.66%)
occurrences (all)	400	286	28
Bacteriuria			
subjects affected / exposed	70 / 829 (8.44%)	54 / 608 (8.88%)	8 / 116 (6.90%)
occurrences (all)	99	78	12
Sinusitis			
subjects affected / exposed	26 / 829 (3.14%)	19 / 608 (3.13%)	2 / 116 (1.72%)
occurrences (all)	27	19	2
Nasopharyngitis			
subjects affected / exposed	30 / 829 (3.62%)	17 / 608 (2.80%)	5 / 116 (4.31%)
occurrences (all)	37	17	5
Upper Respiratory Tract Infection			

alternative assessment type: Non-systematic			
subjects affected / exposed	13 / 829 (1.57%)	23 / 608 (3.78%)	5 / 116 (4.31%)
occurrences (all)	14	23	7
Acute Sinusitis			
subjects affected / exposed	0 / 829 (0.00%)	1 / 608 (0.16%)	0 / 116 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	24 / 829 (2.90%)	14 / 608 (2.30%)	2 / 116 (1.72%)
occurrences (all)	24	15	2
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 829 (0.24%)	2 / 608 (0.33%)	0 / 116 (0.00%)
occurrences (all)	2	2	0
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 829 (0.36%)	4 / 608 (0.66%)	1 / 116 (0.86%)
occurrences (all)	3	6	1
Pneumonia			
subjects affected / exposed	5 / 829 (0.60%)	4 / 608 (0.66%)	0 / 116 (0.00%)
occurrences (all)	6	5	0
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
subjects affected / exposed	3 / 829 (0.36%)	2 / 608 (0.33%)	1 / 116 (0.86%)
occurrences (all)	5	2	1

Non-serious adverse events	botulinum toxin Type A 100U Treatment Cycle 3	botulinum toxin Type A 150U Treatment Cycle 3	botulinum toxin Type A 100U Treatment Cycle 4
Total subjects affected by non-serious adverse events			
subjects affected / exposed	135 / 388 (34.79%)	50 / 179 (27.93%)	86 / 273 (31.50%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 388 (0.00%)	1 / 179 (0.56%)	0 / 273 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Capsular Contracture Associated with Breast Implant			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 388 (0.77%)	3 / 179 (1.68%)	1 / 273 (0.37%)
occurrences (all)	3	3	1
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 388 (1.55%)	2 / 179 (1.12%)	1 / 273 (0.37%)
occurrences (all)	6	2	1
Asthma			
subjects affected / exposed	3 / 388 (0.77%)	1 / 179 (0.56%)	2 / 273 (0.73%)
occurrences (all)	3	1	2
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	7 / 388 (1.80%)	4 / 179 (2.23%)	3 / 273 (1.10%)
occurrences (all)	7	5	3
Psychotic Disorder			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Investigations			
Residual Urine Volume			
subjects affected / exposed	10 / 388 (2.58%)	2 / 179 (1.12%)	4 / 273 (1.47%)
occurrences (all)	11	3	4
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	12 / 388 (3.09%)	2 / 179 (1.12%)	2 / 273 (0.73%)
occurrences (all)	12	2	2
Limb Injury			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences (all)	1	0	1
Femur Fracture			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	1	0	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	2 / 273 (0.73%)
occurrences (all)	1	0	2
Hand Fracture			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 388 (1.03%)	0 / 179 (0.00%)	2 / 273 (0.73%)
occurrences (all)	4	0	2
Trigeminal Neuralgia			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 388 (0.52%)	0 / 179 (0.00%)	2 / 273 (0.73%)
occurrences (all)	2	0	2
Leukocytosis			
subjects affected / exposed	2 / 388 (0.52%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	2	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	7 / 388 (1.80%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences (all)	11	0	2
Eye Inflammation			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 388 (1.29%)	4 / 179 (2.23%)	6 / 273 (2.20%)
occurrences (all)	6	4	6
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	1 / 179 (0.56%)	2 / 273 (0.73%)
occurrences (all)	1	2	2
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 388 (0.52%)	2 / 179 (1.12%)	3 / 273 (1.10%)
occurrences (all)	2	4	3
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Rash			

alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	20 / 388 (5.15%)	16 / 179 (8.94%)	15 / 273 (5.49%)
occurrences (all)	20	19	17
Cystitis Glandularis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	6 / 388 (1.55%)	4 / 179 (2.23%)	1 / 273 (0.37%)
occurrences (all)	6	4	1
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	11 / 388 (2.84%)	4 / 179 (2.23%)	7 / 273 (2.56%)
occurrences (all)	11	4	8
Haematuria			
subjects affected / exposed	8 / 388 (2.06%)	2 / 179 (1.12%)	2 / 273 (0.73%)
occurrences (all)	8	2	2
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	1 / 179 (0.56%)	1 / 273 (0.37%)
occurrences (all)	1	1	1
Bladder Hypertrophy			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Urine Abnormality			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	8 / 388 (2.06%)	3 / 179 (1.68%)	6 / 273 (2.20%)
occurrences (all)	8	4	6
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 388 (2.32%)	6 / 179 (3.35%)	4 / 273 (1.47%)
occurrences (all)	10	6	4
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	6 / 388 (1.55%)	0 / 179 (0.00%)	3 / 273 (1.10%)
occurrences (all)	7	0	3
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 388 (0.77%)	1 / 179 (0.56%)	2 / 273 (0.73%)
occurrences (all)	4	1	2
Tendonitis			
subjects affected / exposed	1 / 388 (0.26%)	2 / 179 (1.12%)	1 / 273 (0.37%)
occurrences (all)	0	1	2
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 388 (0.00%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	107 / 388 (27.58%)	39 / 179 (21.79%)	67 / 273 (24.54%)
occurrences (all)	159	57	90
Bacteriuria			
subjects affected / exposed	32 / 388 (8.25%)	5 / 179 (2.79%)	21 / 273 (7.69%)
occurrences (all)	34	5	25
Sinusitis			
subjects affected / exposed	11 / 388 (2.84%)	4 / 179 (2.23%)	5 / 273 (1.83%)
occurrences (all)	11	4	6
Nasopharyngitis			
subjects affected / exposed	7 / 388 (1.80%)	5 / 179 (2.79%)	5 / 273 (1.83%)
occurrences (all)	7	5	5
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	13 / 388 (3.35%)	4 / 179 (2.23%)	2 / 273 (0.73%)
occurrences (all)	13	4	2
Acute Sinusitis			
subjects affected / exposed	2 / 388 (0.52%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	11 / 388 (2.84%)	1 / 179 (0.56%)	7 / 273 (2.56%)
occurrences (all)	12	1	7
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 388 (0.52%)	0 / 179 (0.00%)	1 / 273 (0.37%)
occurrences (all)	2	0	1
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 388 (0.26%)	0 / 179 (0.00%)	0 / 273 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	6 / 388 (1.55%)	1 / 179 (0.56%)	3 / 273 (1.10%)
occurrences (all)	7	1	3
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
subjects affected / exposed	1 / 388 (0.26%)	1 / 179 (0.56%)	0 / 273 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	botulinum toxin Type A 150U Treatment Cycle 4	botulinum toxin Type A 100U Treatment Cycle 5	botulinum toxin Type A 150U Treatment Cycle 5
Total subjects affected by non-serious adverse events			
subjects affected / exposed	34 / 131 (25.95%)	53 / 185 (28.65%)	35 / 88 (39.77%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Capsular Contracture Associated with Breast Implant			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 131 (1.53%)	1 / 185 (0.54%)	0 / 88 (0.00%)
occurrences (all)	2	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 131 (0.76%)	3 / 185 (1.62%)	0 / 88 (0.00%)
occurrences (all)	1	3	0
Asthma			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 131 (1.53%)	2 / 185 (1.08%)	5 / 88 (5.68%)
occurrences (all)	2	2	5
Psychotic Disorder			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Investigations			
Residual Urine Volume			
subjects affected / exposed	2 / 131 (1.53%)	2 / 185 (1.08%)	1 / 88 (1.14%)
occurrences (all)	2	5	1
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 131 (0.76%)	3 / 185 (1.62%)	2 / 88 (2.27%)
occurrences (all)	1	3	2
Limb Injury			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Femur Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 131 (0.76%)	0 / 185 (0.00%)	1 / 88 (1.14%)
occurrences (all)	1	0	1
Hand Fracture			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	1 / 88 (1.14%)
occurrences (all)	0	0	1
Trigeminal Neuralgia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 131 (1.53%)	1 / 185 (0.54%)	0 / 88 (0.00%)
occurrences (all)	2	1	0
Leukocytosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Eye Inflammation			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 131 (3.05%)	4 / 185 (2.16%)	2 / 88 (2.27%)
occurrences (all)	5	4	2
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 131 (1.53%)	1 / 185 (0.54%)	2 / 88 (2.27%)
occurrences (all)	2	1	2
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 131 (1.53%)	2 / 185 (1.08%)	1 / 88 (1.14%)
occurrences (all)	2	3	1
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0
Rash			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	8 / 131 (6.11%)	7 / 185 (3.78%)	9 / 88 (10.23%)
occurrences (all)	9	10	9
Cystitis Glandularis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	2 / 131 (1.53%)	1 / 185 (0.54%)	1 / 88 (1.14%)
occurrences (all)	3	1	1
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 131 (1.53%)	3 / 185 (1.62%)	3 / 88 (3.41%)
occurrences (all)	2	3	3
Haematuria			
subjects affected / exposed	2 / 131 (1.53%)	3 / 185 (1.62%)	2 / 88 (2.27%)
occurrences (all)	2	3	3
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Bladder Hypertrophy			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Urine Abnormality			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	4 / 131 (3.05%)	3 / 185 (1.62%)	2 / 88 (2.27%)
occurrences (all)	4	3	2
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 131 (2.29%)	2 / 185 (1.08%)	0 / 88 (0.00%)
occurrences (all)	3	2	0
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	2 / 185 (1.08%)	1 / 88 (1.14%)
occurrences (all)	0	2	1
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	1 / 185 (0.54%)	0 / 88 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	1 / 88 (1.14%)
occurrences (all)	1	0	0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	28 / 131 (21.37%)	40 / 185 (21.62%)	20 / 88 (22.73%)
occurrences (all)	39	50	26
Bacteriuria			
subjects affected / exposed	5 / 131 (3.82%)	11 / 185 (5.95%)	7 / 88 (7.95%)
occurrences (all)	6	12	7
Sinusitis			
subjects affected / exposed	0 / 131 (0.00%)	4 / 185 (2.16%)	0 / 88 (0.00%)
occurrences (all)	0	4	0
Nasopharyngitis			
subjects affected / exposed	5 / 131 (3.82%)	6 / 185 (3.24%)	2 / 88 (2.27%)
occurrences (all)	5	6	2
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 131 (0.76%)	7 / 185 (3.78%)	3 / 88 (3.41%)
occurrences (all)	1	8	4
Acute Sinusitis			
subjects affected / exposed	0 / 131 (0.00%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	1 / 131 (0.76%)	4 / 185 (2.16%)	2 / 88 (2.27%)
occurrences (all)	1	5	2
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 131 (0.76%)	1 / 185 (0.54%)	0 / 88 (0.00%)
occurrences (all)	1	1	0
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 131 (0.00%)	2 / 185 (1.08%)	0 / 88 (0.00%)
occurrences (all)	0	2	0
Pneumonia			
subjects affected / exposed	0 / 131 (0.00%)	2 / 185 (1.08%)	0 / 88 (0.00%)
occurrences (all)	0	4	0
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
subjects affected / exposed	1 / 131 (0.76%)	0 / 185 (0.00%)	0 / 88 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	botulinum toxin Type A 100U Treatment Cycle 6	botulinum toxin Type A 150U Treatment Cycle 6	botulinum toxin Type A 100U Treatment Cycle 7
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 139 (30.94%)	10 / 50 (20.00%)	37 / 93 (39.78%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Capsular Contracture Associated with Breast Implant			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	3 / 93 (3.23%)
occurrences (all)	0	0	3
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 139 (1.44%)	2 / 50 (4.00%)	0 / 93 (0.00%)
occurrences (all)	2	2	0
Asthma			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	2 / 139 (1.44%)	0 / 50 (0.00%)	2 / 93 (2.15%)
occurrences (all)	2	0	2
Psychotic Disorder			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Investigations			
Residual Urine Volume			
subjects affected / exposed	2 / 139 (1.44%)	0 / 50 (0.00%)	2 / 93 (2.15%)
occurrences (all)	2	0	1
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 139 (2.16%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences (all)	5	0	1
Limb Injury			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Femur Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Hand Fracture			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 139 (1.44%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	2	0	0
Leukocytosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	1	0	0
Eye Inflammation			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 139 (1.44%)	2 / 50 (4.00%)	1 / 93 (1.08%)
occurrences (all)	2	2	1
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences (all)	1	0	1
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences (all)	1	0	1
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	1	0	0
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Rash			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 139 (6.47%)	3 / 50 (6.00%)	6 / 93 (6.45%)
occurrences (all)	11	3	7
Cystitis Glandularis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	2 / 139 (1.44%)	2 / 50 (4.00%)	2 / 93 (2.15%)
occurrences (all)	2	2	2
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 139 (2.16%)	0 / 50 (0.00%)	2 / 93 (2.15%)
occurrences (all)	3	0	2
Haematuria			
subjects affected / exposed	4 / 139 (2.88%)	0 / 50 (0.00%)	4 / 93 (4.30%)
occurrences (all)	4	0	4
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Bladder Hypertrophy			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Urine Abnormality			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	2 / 139 (1.44%)	1 / 50 (2.00%)	1 / 93 (1.08%)
occurrences (all)	2	1	1
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 139 (2.16%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences (all)	3	0	1
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 139 (0.72%)	1 / 50 (2.00%)	0 / 93 (0.00%)
occurrences (all)	1	1	0
Tendonitis			
subjects affected / exposed	1 / 139 (0.72%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	1	1	0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	28 / 139 (20.14%)	6 / 50 (12.00%)	24 / 93 (25.81%)
occurrences (all)	32	11	26
Bacteriuria			
subjects affected / exposed	10 / 139 (7.19%)	2 / 50 (4.00%)	8 / 93 (8.60%)
occurrences (all)	10	2	9
Sinusitis			
subjects affected / exposed	3 / 139 (2.16%)	0 / 50 (0.00%)	2 / 93 (2.15%)
occurrences (all)	3	0	2
Nasopharyngitis			
subjects affected / exposed	2 / 139 (1.44%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	4	0	0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	2 / 139 (1.44%)	2 / 50 (4.00%)	1 / 93 (1.08%)
occurrences (all)	2	2	2
Acute Sinusitis			
subjects affected / exposed	2 / 139 (1.44%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	4 / 139 (2.88%)	2 / 50 (4.00%)	0 / 93 (0.00%)
occurrences (all)	4	2	0
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	1 / 93 (1.08%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	1 / 139 (0.72%)	2 / 50 (4.00%)	0 / 93 (0.00%)
occurrences (all)	1	3	0
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 139 (0.00%)	0 / 50 (0.00%)	0 / 93 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	botulinum toxin Type A 150U Treatment Cycle 7	botulinum toxin Type A 100U Treatment Cycle 8	botulinum toxin Type A 150U Treatment Cycle 8
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 27 (59.26%)	21 / 69 (30.43%)	9 / 11 (81.82%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Capsular Contracture Associated with Breast Implant			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 27 (3.70%)	1 / 69 (1.45%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	4 / 69 (5.80%)	0 / 11 (0.00%)
occurrences (all)	0	4	0
Asthma			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 27 (3.70%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Psychotic Disorder			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Investigations			
Residual Urine Volume			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 27 (7.41%)	1 / 69 (1.45%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
Limb Injury			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Femur Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hand Fracture			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Trigeminal Neuralgia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 27 (3.70%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	2
Eye Inflammation			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 27 (11.11%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	3	0	0
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 27 (7.41%)	1 / 69 (1.45%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	1 / 27 (3.70%)	1 / 69 (1.45%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 27 (18.52%)	1 / 69 (1.45%)	2 / 11 (18.18%)
occurrences (all)	5	1	2
Cystitis Glandularis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	1 / 27 (3.70%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 27 (3.70%)	2 / 69 (2.90%)	0 / 11 (0.00%)
occurrences (all)	1	2	0
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bladder Hypertrophy			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urine Abnormality			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	2 / 27 (7.41%)	5 / 69 (7.25%)	1 / 11 (9.09%)
occurrences (all)	2	6	1
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	1 / 11 (9.09%)
occurrences (all)	0	2	1
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 27 (3.70%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	4 / 27 (14.81%)	9 / 69 (13.04%)	3 / 11 (27.27%)
occurrences (all)	5	11	3
Bacteriuria			
subjects affected / exposed	2 / 27 (7.41%)	4 / 69 (5.80%)	0 / 11 (0.00%)
occurrences (all)	2	6	0
Sinusitis			
subjects affected / exposed	2 / 27 (7.41%)	2 / 69 (2.90%)	0 / 11 (0.00%)
occurrences (all)	2	2	0
Nasopharyngitis			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	2 / 11 (18.18%)
occurrences (all)	0	1	2
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	1 / 11 (9.09%)
occurrences (all)	0	1	2
Acute Sinusitis			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 27 (0.00%)	2 / 69 (2.90%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 27 (0.00%)	1 / 69 (1.45%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 27 (0.00%)	0 / 69 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	botulinum toxin Type A 100U Treatment Cycle 9	botulinum toxin Type A 150U Treatment Cycle 9	botulinum toxin Type A 100U Treatment Cycle 10
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 48 (37.50%)	6 / 7 (85.71%)	14 / 37 (37.84%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 48 (0.00%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Capsular Contracture Associated with Breast Implant			

subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 48 (4.17%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Asthma			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Psychotic Disorder			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Investigations			
Residual Urine Volume			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 48 (4.17%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences (all)	2	0	1
Limb Injury			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 48 (0.00%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Femur Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 48 (2.08%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hand Fracture			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Leukocytosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	2
Eye Inflammation			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 48 (0.00%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 48 (2.08%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 48 (2.08%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Rash			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 48 (6.25%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences (all)	4	0	1
Cystitis Glandularis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 48 (2.08%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 48 (2.08%)	1 / 7 (14.29%)	1 / 37 (2.70%)
occurrences (all)	1	1	1
Haematuria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bladder Hypertrophy			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Urine Abnormality			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	2 / 48 (4.17%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences (all)	2	0	1
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Tendonitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	13 / 48 (27.08%)	2 / 7 (28.57%)	9 / 37 (24.32%)
occurrences (all)	14	3	10
Bacteriuria			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	3 / 48 (6.25%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	3	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 48 (2.08%)	0 / 7 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	4 / 48 (8.33%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	4	1	0
Acute Sinusitis			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 48 (0.00%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	1 / 7 (14.29%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 48 (0.00%)	0 / 7 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2

Non-serious adverse events	botulinum toxin Type A 150U Treatment Cycle 10	botulinum toxin Type A 100U Treatment Cycle 11	botulinum toxin Type A 100U Treatment Cycle 12
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	12 / 20 (60.00%)	1 / 5 (20.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Capsular Contracture Associated with Breast Implant			

subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychotic Disorder			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Investigations			
Residual Urine Volume			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Fall			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Limb Injury			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Femur Fracture			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Muscle Strain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hand Fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Trigeminal Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Eye Inflammation			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2 (50.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Rash			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cystitis Glandularis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2 (50.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Bladder Hypertrophy			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Urine Abnormality			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	0	3	0
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	1 / 2 (50.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	1 / 2 (50.00%)	4 / 20 (20.00%)	0 / 5 (0.00%)
occurrences (all)	1	5	0
Bacteriuria			
subjects affected / exposed	1 / 2 (50.00%)	2 / 20 (10.00%)	0 / 5 (0.00%)
occurrences (all)	1	2	0
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Acute Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 20 (5.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 20 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	botulinum toxin Type A 100U Treatment Cycle 13		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign Neoplasm of Skin			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Capsular Contracture Associated with Breast Implant			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Asthma			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Oropharyngeal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Psychotic Disorder			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Investigations			
Residual Urine Volume			
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		
Limb Injury			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Femur Fracture			
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	1 / 2 (50.00%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Trigeminal Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Eye disorders			
Cataract			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Eye Inflammation			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nausea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Hyperkeratosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pruritus			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Swelling Face			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Skin Wrinkling			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Rash			

alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Dysuria			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Cystitis Glandularis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Urinary Retention			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Urinary Incontinence			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Bladder Hypertrophy			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Urine Abnormality			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Arthralgia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pain in Extremity			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Musculoskeletal Pain			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Tendonitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Urinary Tract Infection			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Bacteriuria			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Upper Respiratory Tract Infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Acute Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Lower Respiratory Tract Infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Type 2 Diabetes Mellitus			
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 March 2010	1.) The exclusion criterion relating to allergy or sensitivity to any component of the study medication was modified in accordance with the updated Investigator's Brochure. 2) Urine dipstick reagent strip criteria were amended for a patient to be eligible for treatment in the study (patients only needed to be negative for nitrites and leukocyte esterase).
01 March 2011	1) The imputation of missing values for health outcomes questionnaires was removed. 2) The adverse event defined as "residual urine" was renamed "residual urine volume" per MedDRA version 13.1. 3) Additional text was added regarding follow-up diagnostic measures to be performed should there be unclear new findings suggestive of stones or other clinically relevant findings on bladder/kidney ultrasound. 4) It was clarified that patients diagnosed with new or recurrent malignancies, except basal cell carcinoma, should have been discontinued from the study. 5) All references to the intent-to-treat, safety, and per-protocol populations were replaced with the BOTOX-treated population.
01 December 2011	1) The duration of the study was extended from 2 years to 3 years. 2) The imputation method was removed for the primary efficacy variables.
01 August 2012	1) The option to escalate to a dose of 150 U BOTOX was removed. 2) An abortion (spontaneous or nonspontaneous) as a serious adverse event was added. 3) It was clarified that the focus of the analysis will be the repeat treatment data from the 100 U BOTOX group, and data from patients who received 150 U BOTOX are exploratory.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported