



Clinical trial results:

A Multicenter, Open-Label Study to Assess the Long-Term Safety, Tolerability, and Efficacy of Bimekizumab in Adult Subjects With Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2016-003427-30
Trial protocol	DE HU GB BE IT
Global end of trial date	14 November 2023

Results information

Result version number	v1 (current)
This version publication date	24 November 2024
First version publication date	24 November 2024

Trial information

Trial identification

Sponsor protocol code	PS0014
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03598790
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UCB Biopharma SRL
Sponsor organisation address	Allée de la Recherche 60, Brussels, Belgium, 1070
Public contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.com
Scientific contact	Clin Trial Reg & Results Disclosure, UCB BIOSCIENCES GmbH, clinicaltrials@ucb.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	13 December 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 November 2023
Global end of trial reached?	Yes
Global end of trial date	14 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assess the long-term safety and tolerability of bimekizumab in adult subjects with moderate to severe chronic plaque psoriasis

Protection of trial subjects:

During the conduct of the study all participants were closely monitored.

Background therapy:

Background therapy as permitted in the protocol.

Evidence for comparator:

Not applicable

Actual start date of recruitment	05 September 2018
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	Australia: 36
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	Canada: 200
Country: Number of subjects enrolled	Germany: 132
Country: Number of subjects enrolled	Hungary: 90
Country: Number of subjects enrolled	Italy: 3
Country: Number of subjects enrolled	Japan: 154
Country: Number of subjects enrolled	Korea, Republic of: 11
Country: Number of subjects enrolled	Poland: 396
Country: Number of subjects enrolled	Russian Federation: 50
Country: Number of subjects enrolled	Taiwan: 6
Country: Number of subjects enrolled	United Kingdom: 12
Country: Number of subjects enrolled	United States: 259
Worldwide total number of subjects	1353
EEA total number of subjects	625

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)	1236
From 65 to 84 years	117
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started to enroll participants in September 2018 and concluded in November 2023. Participant flow refers to the Cohort A Safety Set, Cohort A OLE2 Period Set and Cohort B Safety Set. Participants who enrolled in PS0014 after completion of Phase 3 feeder studies were included in Cohort A. An additional Cohort B was added in Japan.

Pre-assignment

Screening details:

Cohort A has Treatment Period (TP) (144 wks) followed by SFU Visit (20 wks after final dose). Cohort B has Screening Period (2 to 5 wks) and TP (144 wks) followed by SFU Visit (20 wks after final dose). After Protocol Amendment 3.3 (US) and 3.4 (Canada), 48-week OLE2 Period followed by SFU2 Visit (20 wks after final dose) was added in Cohort A.

Period 1

Period 1 title	Treatment Period (TP): Wk0-Wk144
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A: BKZ 320 mg Q8W

Arm description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder studies (PS0008 [NCT03412747], PS0009 [NCT03370133], and PS0013 [NCT03410992]), participants were randomized to receive BKZ 320 milligrams (mg) subcutaneously (sc) every 8 weeks (Q8W) in this study during the 144-week (wk) Treatment Period. The BKZ 320 mg Q8W group consisted of all participants who received only Q8W during PS0014 study and did not switch dosing regimen at any time point.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	Cohort A: BKZ 320 mg Q4W/Q8W
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Arm description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder study, participants were randomized to receive BKZ 320 mg sc every 4 weeks (Q4W) in this study during the 144-week Treatment Period. The participants switched to BKZ 320 mg Q8W as per protocol. The BKZ 320mg Q4W/Q8W group consisted of all participants who switched from Q4W to Q8W dosing at any of the scheduled switching time points during the study.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	Cohort A: BKZ 320 mg Q4W
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Arm description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder study, participants were randomized to receive BKZ 320 mg sc Q4W in this study during the 144-week Treatment Period. The BKZ 320 mg Q4W group consisted of participants who discontinued prior to the planned change of dosing interval from BKZ 320 mg Q4W to BKZ 320 mg Q8W.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	Cohort B: PSO BKZ Total
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Arm description:

Participants with chronic plaque psoriasis (PSO) in Cohort B received BKZ 320 mg sc Q4W until Week 16 and 320 mg Q8W thereafter through Week 40. At Week 48, Cohort B participants with chronic plaque PSO continued BKZ 320 mg Q8W up to Week 144. If the participant's dosing interval had changed to BKZ 320 mg Q4W under Protocol Amendment 1.2, the participant's dosing interval changed to BKZ 320 mg Q8W at the next scheduled clinic visit after implementation of Protocol Amendment 3.2.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	Cohort B: EP BKZ Total
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Arm description:

Participants with erythrodermic psoriasis (EP) in Cohort B received BKZ 320 mg sc Q4W until Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	Cohort B: GPP BKZ Total
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Arm description:

Participants with generalized pustular psoriasis (GPP) in Cohort B received BKZ 320 mg sc Q4W until Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Number of subjects in period 1	Cohort A: BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W/Q8W	Cohort A: BKZ 320 mg Q4W
Started	384	833	70
Completed	326	746	0
Not completed	58	87	70
Physician decision	-	-	1
Sponsor's Decision	1	2	-
Covid-19 Pandemic Circumstances	-	3	1
Patient Did Not Comply With Safety Precautions	1	-	-
Long IP pause; Investigator decided termination	1	-	-
Completed treatment but missed Week 144 visit	3	1	-
Non-Compliance	-	1	-
The Subject Can't Visit the Hospital Anymore	-	-	-
COVID-19 restrictions; Subject unable to return	-	-	1
Adverse event, non-fatal	24	33	24
Pregnancy	1	-	-
Site Closure; Subject did not want to transfer	-	-	1
Non-Compliance-PI early terminated the subject	-	-	1
Lost to follow-up	7	11	14
Unplanned Elective Surgery	-	1	-
Consent withdrawn by subject	14	26	17
Lack of efficacy	4	7	5
Protocol deviation	1	2	4
Withdrawn By Sponsor	1	-	-
Subject Withdraw Consent (Fear Of Another Ae)	-	-	1

Number of subjects in period 1	Cohort B: PSO BKZ Total	Cohort B: EP BKZ Total	Cohort B: GPP BKZ Total
Started	45	11	10
Completed	38	10	8
Not completed	7	1	2
Physician decision	-	-	-

Sponsor's Decision	-	-	-
Covid-19 Pandemic Circumstances	-	-	-
Patient Did Not Comply With Safety Precautions	-	-	-
Long IP pause; Investigator decided termination	-	-	-
Completed treatment but missed Week 144 visit	-	-	-
Non-Compliance	-	-	-
The Subject Can't Visit the Hospital Anymore	1	-	-
COVID-19 restrictions; Subject unable to return	-	-	-
Adverse event, non-fatal	3	1	2
Pregnancy	-	-	-
Site Closure; Subject did not want to transfer	-	-	-
Non-Compliance-PI early terminated the subject	-	-	-
Lost to follow-up	-	-	-
Unplanned Elective Surgery	-	-	-
Consent withdrawn by subject	1	-	-
Lack of efficacy	2	-	-
Protocol deviation	-	-	-
Withdrawn By Sponsor	-	-	-
Subject Withdraw Consent (Fear Of Another Ae)	-	-	-

Period 2

Period 2 title	OLE2 Period: Wk 144/OLE2 BL- OLE2 Wk 48
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A: Group A BKZ 320 mg Q8W

Arm description:

Participants who completed the Treatment Period (Week 0 to Week 144) were directly rolled over to the Open-Label Extension 2 (OLE2) Period. Participants continued receiving BKZ 320 mg sc Q8W for 40 additional weeks (from Week 144/OLE2 Period Baseline Visit to OLE2 Period Week 48).

Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	Cohort A: Group B BKZ 320 mg Q8W
Arm description: Participants who had completed the Treatment Period Week 144 Visit and who were in the SFU or had completed the SFU at the time of Protocol Amendment 3.3 and 3.4 implementation reinitiated BKZ treatment in the OLE2 Period after 4-week OLE2 Screening Period. Participants in OLE2 Period Group B with an IGA score <3 upon entry received BKZ 320 mg sc Q8W from the Week 144/OLE2 Period Baseline Visit to OLE2 Period Week 48.	
Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Arm title	Cohort A: Group B BKZ 320 mg Q4W/Q8W
Arm description: Participants who had completed the Treatment Period Week 144 Visit and who were in the Safety Follow-Up (SFU) or had completed the SFU at the time of Protocol Amendment 3.3 and 3.4 implementation reinitiated BKZ treatment in the OLE2 Period after 4-week OLE2 Screening Period. Participants with an Investigator's Global Assessment (IGA) score greater than equal to (>=) 3 upon entry in the OLE2 Period received BKZ 320 mg sc Q4W for the first 16 weeks, and then switched to BKZ 320 mg Q8W until OLE2 Period Week 48.	
Arm type	Experimental
Investigational medicinal product name	Bimekizumab
Investigational medicinal product code	UCB4940
Other name	Bimzelx®
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received BKZ 320 mg at pre-specified time-points.

Number of subjects in period 2 ^[1]	Cohort A: Group A BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q4W/Q8W
	Started	226	51
Completed	216	49	39
Not completed	10	2	2
Adverse event, non-fatal	2	1	2
Pt Cannot Commit To Study Schedule	1	-	-
Lost to follow-up	4	-	-
Consent withdrawn	1	1	-
Lack of efficacy	2	-	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants who provided consent to continue in OLE2 Period.

Baseline characteristics

Reporting groups

Reporting group title	Cohort A: BKZ 320 mg Q8W
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Reporting group description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder studies (PS0008 [NCT03412747], PS0009 [NCT03370133], and PS0013 [NCT03410992]), participants were randomized to receive BKZ 320 milligrams (mg) subcutaneously (sc) every 8 weeks (Q8W) in this study during the 144-week (wk) Treatment Period. The BKZ 320 mg Q8W group consisted of all participants who received only Q8W during PS0014 study and did not switch dosing regimen at any time point.

Reporting group title	Cohort A: BKZ 320 mg Q4W/Q8W
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Reporting group description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder study, participants were randomized to receive BKZ 320 mg sc every 4 weeks (Q4W) in this study during the 144-week Treatment Period. The participants switched to BKZ 320 mg Q8W as per protocol. The BKZ 320mg Q4W/Q8W group consisted of all participants who switched from Q4W to Q8W dosing at any of the scheduled switching time points during the study.

Reporting group title	Cohort A: BKZ 320 mg Q4W
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Reporting group description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder study, participants were randomized to receive BKZ 320 mg sc Q4W in this study during the 144-week Treatment Period. The BKZ 320 mg Q4W group consisted of participants who discontinued prior to the planned change of dosing interval from BKZ 320 mg Q4W to BKZ 320 mg Q8W.

Reporting group title	Cohort B: PSO BKZ Total
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Reporting group description:

Participants with chronic plaque psoriasis (PSO) in Cohort B received BKZ 320 mg sc Q4W until Week 16 and 320 mg Q8W thereafter through Week 40. At Week 48, Cohort B participants with chronic plaque PSO continued BKZ 320 mg Q8W up to Week 144. If the participant's dosing interval had changed to BKZ 320 mg Q4W under Protocol Amendment 1.2, the participant's dosing interval changed to BKZ 320 mg Q8W at the next scheduled clinic visit after implementation of Protocol Amendment 3.2.

Reporting group title	Cohort B: EP BKZ Total
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Reporting group description:

Participants with erythrodermic psoriasis (EP) in Cohort B received BKZ 320 mg sc Q4W until Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Reporting group title	Cohort B: GPP BKZ Total
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Reporting group description:

Participants with generalized pustular psoriasis (GPP) in Cohort B received BKZ 320 mg sc Q4W until Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Reporting group values	Cohort A: BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W/Q8W	Cohort A: BKZ 320 mg Q4W
Number of subjects	384	833	70
Age Categorical Units: participants			
18 - <65 years	349	757	68
65 - <85 years	35	76	2
>= 85 years	0	0	0
Age Continuous Units: years			
arithmetic mean	45.3	45.5	45.4
standard deviation	± 13.7	± 13.2	± 13.4

Sex: Female, Male			
Units: participants			
Female	118	221	24
Male	266	612	46

Reporting group values	Cohort B: PSO BKZ Total	Cohort B: EP BKZ Total	Cohort B: GPP BKZ Total
Number of subjects	45	11	10
Age Categorical			
Units: participants			
18 - <65 years	42	10	10
65 - <85 years	3	1	0
>= 85 years	0	0	0
Age Continuous			
Units: years			
arithmetic mean	48.8	55.3	46.0
standard deviation	± 11.5	± 11.9	± 12.5
Sex: Female, Male			
Units: participants			
Female	9	0	4
Male	36	11	6

Reporting group values	Total		
Number of subjects	1353		
Age Categorical			
Units: participants			
18 - <65 years	1236		
65 - <85 years	117		
>= 85 years	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: participants			
Female	376		
Male	977		

End points

End points reporting groups

Reporting group title	Cohort A: BKZ 320 mg Q8W
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Reporting group description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder studies (PS0008 [NCT03412747], PS0009 [NCT03370133], and PS0013 [NCT03410992]), participants were randomized to receive BKZ 320 milligrams (mg) subcutaneously (sc) every 8 weeks (Q8W) in this study during the 144-week (wk) Treatment Period. The BKZ 320 mg Q8W group consisted of all participants who received only Q8W during PS0014 study and did not switch dosing regimen at any time point.

Reporting group title	Cohort A: BKZ 320 mg Q4W/Q8W
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Reporting group description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder study, participants were randomized to receive BKZ 320 mg sc every 4 weeks (Q4W) in this study during the 144-week Treatment Period. The participants switched to BKZ 320 mg Q8W as per protocol. The BKZ 320mg Q4W/Q8W group consisted of all participants who switched from Q4W to Q8W dosing at any of the scheduled switching time points during the study.

Reporting group title	Cohort A: BKZ 320 mg Q4W
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Reporting group description:

Based on the PASI90 response and the treatment/dose the participant was receiving in the feeder study, participants were randomized to receive BKZ 320 mg sc Q4W in this study during the 144-week Treatment Period. The BKZ 320 mg Q4W group consisted of participants who discontinued prior to the planned change of dosing interval from BKZ 320 mg Q4W to BKZ 320 mg Q8W.

Reporting group title	Cohort B: PSO BKZ Total
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Reporting group description:

Participants with chronic plaque psoriasis (PSO) in Cohort B received BKZ 320 mg sc Q4W until Week 16 and 320 mg Q8W thereafter through Week 40. At Week 48, Cohort B participants with chronic plaque PSO continued BKZ 320 mg Q8W up to Week 144. If the participant's dosing interval had changed to BKZ 320 mg Q4W under Protocol Amendment 1.2, the participant's dosing interval changed to BKZ 320 mg Q8W at the next scheduled clinic visit after implementation of Protocol Amendment 3.2.

Reporting group title	Cohort B: EP BKZ Total
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Reporting group description:

Participants with erythrodermic psoriasis (EP) in Cohort B received BKZ 320 mg sc Q4W until Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Reporting group title	Cohort B: GPP BKZ Total
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Reporting group description:

Participants with generalized pustular psoriasis (GPP) in Cohort B received BKZ 320 mg sc Q4W until Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Reporting group title	Cohort A: Group A BKZ 320 mg Q8W
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Reporting group description:

Participants who completed the Treatment Period (Week 0 to Week 144) were directly rolled over to the Open-Label Extension 2 (OLE2) Period. Participants continued receiving BKZ 320 mg sc Q8W for 40 additional weeks (from Week 144/OLE2 Period Baseline Visit to OLE2 Period Week 48).

Reporting group title	Cohort A: Group B BKZ 320 mg Q8W
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Reporting group description:

Participants who had completed the Treatment Period Week 144 Visit and who were in the SFU or had completed the SFU at the time of Protocol Amendment 3.3 and 3.4 implementation reinitiated BKZ treatment in the OLE2 Period after 4-week OLE2 Screening Period. Participants in OLE2 Period Group B with an IGA score <3 upon entry received BKZ 320 mg sc Q8W from the Week 144/OLE2 Period Baseline Visit to OLE2 Period Week 48.

Reporting group title	Cohort A: Group B BKZ 320 mg Q4W/Q8W
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Reporting group description:

Participants who had completed the Treatment Period Week 144 Visit and who were in the Safety Follow-Up (SFU) or had completed the SFU at the time of Protocol Amendment 3.3 and 3.4 implementation reinitiated BKZ treatment in the OLE2 Period after 4-week OLE2 Screening Period. Participants with an Investigator's Global Assessment (IGA) score greater than equal to (>=) 3 upon

entry in the OLE2 Period received BKZ 320 mg sc Q4W for the first 16 weeks, and then switched to BKZ 320 mg Q8W until OLE2 Period Week 48.

Subject analysis set title	Cohort A: BKZ 320 mg Q8W
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received BKZ 320 mg Q8W and who switched from Q4W to Q8W dosing at any of the scheduled time points during the 144-week Treatment Period. The participants who switched from BKZ 320 mg Q4W to Q8W during the study were included in both the BKZ 320 mg Q4W group and the BKZ 320 mg Q8W group.

Subject analysis set title	Cohort A: BKZ 320 mg Q4W
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received BKZ 320 mg Q4W during the 144-week Treatment Period. The participants who switched from BKZ 320 mg Q4W to Q8W during the study were included in both the BKZ 320 mg Q4W group and the BKZ 320 mg Q8W group.

Primary: Number of Treatment Emergent Adverse Events (TEAEs) adjusted by duration of subject exposure to Investigational Medicinal Product (IMP)

End point title	Number of Treatment Emergent Adverse Events (TEAEs) adjusted by duration of subject exposure to Investigational Medicinal Product (IMP) ^{[1][2]}
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End point description:

The number of TEAEs adjusted by duration of exposure to study treatment were scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to first occurrence of the AE being considered. If a participant had no events, the total time at risk was used. CA-SS -All Cohort A participants who received at least 1 dose of the IMP in this study. Cohort A OLE2 Period Set (CA-OL2S)-All participants who received at least 1 dose of BKZ in the OLE2 Period. Cohort B PSO SS-All participants with a diagnosis of PSO disease at Baseline (BL). Cohort B EP-SS-All participants with a diagnosis of EP disease at Baseline. Cohort B GPP-SS-All participants with a diagnosis of GPP disease at Baseline.

End point type	Primary
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End point timeframe:

From Baseline up to 165 weeks for each study participant not entering the OLE2 Period and up to 212 weeks for participants entering OLE2 Period

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 formal statistical hypothesis testing was planned for this study. Results were summarized as descriptive statistics only.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The safety endpoints used combined arms of Cohort A for data reporting.

End point values	Cohort A: Group A BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q4W/Q8W	Cohort B: PSO BKZ Total
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	226	51	41	45
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	79.02 (65.97 to 93.89)	77.11 (51.64 to 110.74)	73.78 (47.75 to 108.92)	244.08 (178.03 to 326.60)

End point values	Cohort B: EP BKZ Total	Cohort B: GPP BKZ Total	Cohort A: BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W
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Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	10	1217	903
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	328.25 (163.86 to 587.33)	188.71 (86.29 to 358.22)	97.83 (91.73 to 104.22)	179.68 (166.62 to 193.49)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Serious Adverse Events (SAEs) adjusted by duration of subject exposure to IMP

End point title	Number of Serious Adverse Events (SAEs) adjusted by duration of subject exposure to IMP ^[3]
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End point description:

The number of SAEs adjusted by duration of exposure to study treatment were scaled such that it provides an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no events, the total time at risk is used. CA-SS -All Cohort A participants who received at least 1 dose of the IMP in this study. CA-OL2S-All participants who received at least 1 dose of BKZ in the OLE2 Period. Cohort B PSO SS-All participants with a diagnosis of PSO disease at Baseline. Cohort B EP-SS-All participants with a diagnosis of EP disease at Baseline. Cohort B GPP-SS-All participants with a diagnosis of GPP disease at Baseline.

End point type	Secondary
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End point timeframe:

From Baseline up to 165 weeks for each study participant not entering the OLE2 Period and up to 212 weeks for participants entering OLE2 Period

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The safety endpoints used combined arms of Cohort A for data reporting.

End point values	Cohort A: Group A BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q4W/Q8W	Cohort B: PSO BKZ Total
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	226	51	41	45
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	4.44 (2.22 to 7.95)	9.05 (2.94 to 21.13)	8.93 (2.43 to 22.86)	5.86 (2.36 to 12.08)

End point values	Cohort B: EP BKZ Total	Cohort B: GPP BKZ Total	Cohort A: BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	10	1217	903
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	19.51 (6.34 to 45.54)	7.56 (0.92 to 27.32)	5.24 (4.36 to 6.25)	6.72 (5.19 to 8.56)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of TEAEs leading to withdrawal adjusted by duration of subject exposure to IMP

End point title	Number of TEAEs leading to withdrawal adjusted by duration of subject exposure to IMP ^[4]
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End point description:

The number of TEAEs leading to withdrawal adjusted by duration of exposure to study treatment were scaled such that it provided an incidence rate per 100 patient-years. If a participant had multiple events, the time of exposure was calculated to the first occurrence of the AE being considered. If a participant had no events, the total time at risk was used. CA-SS -All Cohort A participants who received at least 1 dose of the IMP in this study. CA-OL2S-All participants who received at least 1 dose of BKZ in the OLE2 Period. Cohort B PSO SS-All participants with a diagnosis of PSO disease at Baseline. Cohort B EP-SS-All participants with a diagnosis of EP disease at Baseline. Cohort B GPP-SS-All participants with a diagnosis of GPP disease at Baseline.

End point type	Secondary
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End point timeframe:

From Baseline up to 165 weeks for each study participant not entering the OLE2 Period and up to 212 weeks for participants entering OLE2 Period

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The safety endpoints used combined arms of Cohort A for data reporting.

End point values	Cohort A: Group A BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q8W	Cohort A: Group B BKZ 320 mg Q4W/Q8W	Cohort B: PSO BKZ Total
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	226	51	41	45
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	0.79 (0.10 to 2.86)	1.77 (0.04 to 9.86)	4.37 (0.53 to 15.79)	2.42 (0.50 to 7.08)

End point values	Cohort B: EP BKZ Total	Cohort B: GPP BKZ Total	Cohort A: BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	11	10	1217	903
Units: no. of new events per 100 subject-years				
number (confidence interval 95%)	3.27 (0.08 to 18.19)	7.68 (0.93 to 27.74)	2.11 (1.57 to 2.76)	2.59 (1.69 to 3.80)

Statistical analyses

No statistical analyses for this end point

Secondary: Psoriasis Area Severity Index 90 (PASI90) response at Week 144 (Non-responder imputation)

End point title	Psoriasis Area Severity Index 90 (PASI90) response at Week 144 (Non-responder imputation) ^[5]
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End point description:

The PASI90 response assessments were based on improvement (reduction) of at least 90% in the PASI score compared to Baseline. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for redness, thickness, and scaling for each of the 4 body areas with score of 0 (clear) to 4 (very marked). Determining the percentage of skin covered with PSO for each of the body areas and converting to a 0 to 6 scale. Final PASI=average redness, thickness, and scaliness of the psoriatic skin lesions, multiplied by involved psoriasis area score of the respective section, and weighted by the percentage of the person's affected skin for respective section. The minimum possible PASI score is 0= no disease, the maximum score is 72= maximal disease. Cohort A FAS, Cohort B Psoriasis FAS were used. Study participants who had missing data at Week 144 were treated as though they did not respond to treatment using Non-responder imputation (NRI) method.

End point type	Secondary
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End point timeframe:

Week 144 compared to Baseline of Feeder study for Cohort A and Baseline of PS0014 for Cohort B

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The data for other arms have been reported as a separate endpoint.

End point values	Cohort A: BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W/Q8W	Cohort A: BKZ 320 mg Q4W	Cohort B: PSO BKZ Total
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	384	832	70	45
Units: percentage of participants				
number (not applicable)	77.6	80.2	0	73.3

Statistical analyses

No statistical analyses for this end point

Secondary: Psoriasis Area Severity Index 90 (PASI90) response at Week 144 (Observed Case)

End point title	Psoriasis Area Severity Index 90 (PASI90) response at Week 144 (Observed Case) ^[6]
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End point description:

PASI90 response assessments were based on improvement (reduction) of at least 90% in PASI score compared to Baseline. Body divided into 4 areas: head, arms, trunk to groin, and legs to top of buttocks. Assignment of an average score for redness, thickness, and scaling for each of 4 body areas with score of 0 (clear) to 4 (very marked). Determining percentage of skin covered with PSO for each of body areas and converting to a 0 to 6 scale. Final PASI=average redness, thickness, and scaliness of psoriatic skin lesions, multiplied by involved psoriasis area score of respective section, and weighted by percentage of person's affected skin for respective section. Minimum score is 0= no disease, maximum score is 72= maximal disease. Cohort B GPP FAS included study participants with GPP at Baseline. Cohort B EP FAS included study participants with EP at Baseline. Only study participants with available data who had not discontinued study treatment at Week 144 were considered for the analysis.

End point type	Secondary
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End point timeframe:

Week 144 compared to Baseline of PS0014 for Cohort B

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The data for other arms have been reported as a separate endpoint.

End point values	Cohort B: EP BKZ Total	Cohort B: GPP BKZ Total		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: percentage of participants				
number (not applicable)	90.0	85.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Investigator´s Global Assessment (IGA) 0/1 response at Week 144 (Non-responder imputation)

End point title	Investigator´s Global Assessment (IGA) 0/1 response at Week 144 (Non-responder imputation) ^[7]
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End point description:

Investigator assessed overall severity of psoriasis using the following 5-point scale: 0 = Clear (no signs of psoriasis; post-inflammatory hyperpigmentation may be present); 1= Almost clear (no thickening; normal to pink coloration; no to minimal focal scaling); 2= Mild (just detectable to mild thickening; pink to light red coloration; predominately fine scaling); 3= Moderate (clearly distinguishable to moderate thickening; dull to bright red coloration; moderate scaling); 4= Severe (Severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions). IGA response -IGA score of clear [0] or almost clear [1] with at least two category improvement from Baseline at visit timepoint. Cohort A FAS: participants who received at least 1 dose of IMP and had valid efficacy measurement for PASI at BL of feeder study and at BL of this study. Cohort B Psoriasis FAS: participants with chronic plaque PSO at BL. NRI method was used.

End point type	Secondary
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End point timeframe:

Week 144 compared to Baseline of Feeder study for Cohort A and Baseline of PS0014 for Cohort B

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The data for other arms have been reported as a separate endpoint.

End point values	Cohort A: BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W/Q8W	Cohort A: BKZ 320 mg Q4W	Cohort B: PSO BKZ Total
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	384	832	70	45
Units: percentage of participants				
number (not applicable)	76.8	79.0	0	60.0

Statistical analyses

No statistical analyses for this end point

Secondary: Investigator´s Global Assessment (IGA) 0/1 response at Week 144 (Observed Case)

End point title	Investigator´s Global Assessment (IGA) 0/1 response at Week 144 (Observed Case) ^[8]
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End point description:

The Investigator assessed the overall severity of psoriasis using the following 5-point scale (five-point IGA): 0 = Clear (no signs of psoriasis; post-inflammatory hyperpigmentation may be present); 1= Almost clear (no thickening; normal to pink coloration; no to minimal focal scaling); 2= Mild (just detectable to mild thickening; pink to light red coloration; predominately fine scaling); 3= Moderate (clearly distinguishable to moderate thickening; dull to bright red coloration; moderate scaling); 4= Severe (Severe thickening with hard edges; bright to deep dark red coloration; severe/coarse scaling covering almost all or all lesions). IGA response -IGA score of 0 or 1 at Week 144. Cohort B GPP FAS included study participants with GPP at Baseline. Cohort B EP FAS included study participants with EP at Baseline. Only study participants with available data who had not discontinued study treatment at Week 144 were considered for the analysis.

End point type	Secondary
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End point timeframe:

Week 144 for Cohort B EP and GPP groups

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: The data for other arms have been reported as a separate endpoint.

End point values	Cohort B: EP BKZ Total	Cohort B: GPP BKZ Total		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	10		
Units: percentage of participants				
number (not applicable)	80.0	85.7		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Baseline up to 165 weeks for each study participant not entering the OLE2 Period and up to 212 weeks for participants entering OLE2 Period

Adverse event reporting additional description:

TEAEs were defined as events that have a start date on or following the first administration of study treatment in PS0014 through the final administration of study treatment + 140 days (covering the 20-week SFU Period). Cohort A OLE2 Period Set (CA-OL2S) included all participants who received at least 1 dose of BKZ in the OLE2 Period. SS was used.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	Cohort A: BKZ 320 mg Q8W
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Reporting group description:

Participants who received BKZ 320 mg Q8W and who switched from Q4W to Q8W dosing at any of the scheduled time points during the 144-week Treatment Period. The participants who switched from bimekizumab 320 mg Q4W to Q8W during the study were included in both the BKZ 320 mg Q4W group and the BKZ 320 mg Q8W group. All the adverse events occurred during the BKZ 320 mg Q8W treatment at any timepoint of the study were included in this arm.

Reporting group title	Cohort A: Group A BKZ 320 mg Q8W
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Reporting group description:

Participants who completed the Treatment Period (Week 0 to Week 144) were directly rolled over to the Open-Label Extension 2 (OLE2) Period. Participants continued receiving BKZ 320 mg sc Q8W for 40 additional weeks (from Week 144/OLE2 Period Baseline Visit to OLE2 Period Week 48).

Reporting group title	Cohort A: BKZ 320 mg Q4W
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Reporting group description:

Participants who received BKZ 320 mg Q4W during the 144-week Treatment Period. The participants who switched from bimekizumab 320 mg Q4W to Q8W during the study were included in both the BKZ 320 mg Q4W group and the BKZ 320 mg Q8W group. All the adverse events occurred during the BKZ 320 mg Q4W treatment at any timepoint of the study were included in this arm.

Reporting group title	Cohort B: EP BKZ Total
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Reporting group description:

Participants with erythrodermic psoriasis (EP) in Cohort B received BKZ 320 mg sc Q4W until Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Reporting group title	Cohort B: PSO BKZ Total
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Reporting group description:

Participants with chronic plaque psoriasis (PSO) in Cohort B received BKZ 320 mg sc Q4W until Week 16 and 320 mg Q8W thereafter through Week 40. At Week 48, Cohort B participants with chronic plaque PSO continued BKZ 320 mg Q8W up to Week 144. If the participant's dosing interval had changed to BKZ 320 mg Q4W under Protocol Amendment 1.2, the participant's dosing interval changed to BKZ 320 mg Q8W at the next scheduled clinic visit after implementation of Protocol Amendment 3.2.

Reporting group title	Cohort A: Group B BKZ 320 mg Q4W/Q8W
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Reporting group description:

Participants who had completed the Treatment Period Week 144 Visit and who were in the Safety Follow-Up (SFU) or had completed the SFU at the time of Protocol Amendment 3.3 and 3.4 implementation reinitiated BKZ treatment in the OLE2 Period after 4-week OLE2 Screening Period. Participants with an Investigator's Global Assessment (IGA) score greater than equal to (\geq) 3 upon entry in the OLE2 Period received BKZ 320 mg sc Q4W for the first 16 weeks, and then switched to BKZ 320 mg Q8W until OLE2 Period Week 48.

Reporting group title	Cohort B: GPP BKZ Total
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Reporting group description:

Participants with generalized pustular psoriasis (GPP) in Cohort B received BKZ 320 mg sc Q4W until

Week 16. Based on IGA response, participants received either BKZ 320 mg sc Q4W or BKZ 320 mg sc Q8W up to Week 144.

Reporting group title	Cohort A: Group B BKZ 320 mg Q8W
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Reporting group description:

Participants who had completed the Treatment Period Week 144 Visit and who were in the SFU or had completed the SFU at the time of Protocol Amendment 3.3 and 3.4 implementation reinitiated BKZ treatment in the OLE2 Period after 4-week OLE2 Screening Period. Participants in OLE2 Period Group B with an IGA score <3 upon entry received BKZ 320 mg sc Q8W from the Week 144/OLE2 Period Baseline Visit to OLE2 Period Week 48.

Serious adverse events	Cohort A: BKZ 320 mg Q8W	Cohort A: Group A BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W
Total subjects affected by serious adverse events			
subjects affected / exposed	124 / 1217 (10.19%)	11 / 226 (4.87%)	65 / 903 (7.20%)
number of deaths (all causes)	9	0	6
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Breast cancer stage I			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 breast carcinoma			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Colon cancer			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colon cancer metastatic			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Adenocarcinoma of colon			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Colorectal adenocarcinoma			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Thyroid neoplasm			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Colorectal cancer metastatic			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Tongue neoplasm benign			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Lip and/or oral cavity cancer			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Brain neoplasm			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Adenocarcinoma pancreas			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 lung			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Prostate cancer stage I			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Metastatic bronchial carcinoma			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 cell lung cancer metastatic			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Basal cell carcinoma			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
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	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Lipoma			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Papillary thyroid cancer			
subjects affected / exposed	2 / 1217 (0.16%)	0 / 226 (0.00%)	0 / 903 (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
Thyroid cancer			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Plasma cell myeloma			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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 tract adenoma			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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 cell lung cancer			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			
Aortic aneurysm			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Femoral artery embolism			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
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			
Hip arthroplasty			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			

Abortion spontaneous			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy on oral contraceptive			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent-graft endoleak			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Ovarian cyst			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 prolapse			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine polyp			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital haemorrhage			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Chronic obstructive pulmonary disease			
subjects affected / exposed	4 / 1217 (0.33%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Asthma			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Laryngeal ulceration			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Pharyngeal ulceration			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	2 / 903 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Acute respiratory failure			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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 / 1217 (0.00%)	1 / 226 (0.44%)	0 / 903 (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			
Bipolar I disorder			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dependence			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Suicidal ideation			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Suicide attempt			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			

Meniscus injury			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 injury			
subjects affected / exposed	2 / 1217 (0.16%)	0 / 226 (0.00%)	0 / 903 (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
Pneumothorax traumatic			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	2 / 1217 (0.16%)	0 / 226 (0.00%)	0 / 903 (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
Femoral neck fracture			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
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 fracture			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Hand fracture			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Patella fracture			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
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 rupture			
subjects affected / exposed	3 / 1217 (0.25%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Road traffic accident			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Procedural pain			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Head injury			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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	2 / 1217 (0.16%)	0 / 226 (0.00%)	0 / 903 (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 injury			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			
Wolff-Parkinson-White syndrome			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Hypertensive cardiomyopathy			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Coronary artery disease			
subjects affected / exposed	2 / 1217 (0.16%)	0 / 226 (0.00%)	0 / 903 (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	1 / 1217 (0.08%)	1 / 226 (0.44%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute myocardial infarction			
subjects affected / exposed	4 / 1217 (0.33%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	3 / 1217 (0.25%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			

subjects affected / exposed	3 / 1217 (0.25%)	3 / 226 (1.33%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	3 / 903 (0.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Systolic dysfunction			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Tachycardia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	2 / 903 (0.22%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 2
Atrial flutter			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Pulseless electrical activity			
subjects affected / exposed	0 / 1217 (0.00%)	1 / 226 (0.44%)	0 / 903 (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 failure			
subjects affected / exposed	0 / 1217 (0.00%)	1 / 226 (0.44%)	0 / 903 (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
Ventricular tachycardia			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral ischaemia			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular disorder			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	2 / 1217 (0.16%)	0 / 226 (0.00%)	0 / 903 (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
Intracranial pressure increased			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Hemiplegic migraine			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Relapsing-remitting multiple sclerosis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Seizure			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitic myelopathy			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Haemorrhagic anaemia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic diathesis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 acute			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Anal prolapse			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Large intestine polyp			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Crohn's disease			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Duodenal ulcer			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Diverticulum intestinal			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Chronic gastritis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Oroantral fistula			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Enteritis			
subjects affected / exposed	0 / 1217 (0.00%)	1 / 226 (0.44%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			

subjects affected / exposed	2 / 1217 (0.16%)	1 / 226 (0.44%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Nausea			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			
Cholecystocholangitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
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 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
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 acute			
subjects affected / exposed	1 / 1217 (0.08%)	1 / 226 (0.44%)	0 / 903 (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
Cholelithiasis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Bile duct obstruction			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Drug-induced liver injury			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis atopic			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythrodermic psoriasis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pustular psoriasis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	2 / 903 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 failure			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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 colic			

subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Endocrine disorders			
Hyperparathyroidism primary			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Osteitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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

Inclusion body myositis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Osteoarthritis			
subjects affected / exposed	2 / 1217 (0.16%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal osteoarthritis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kyphosis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Tendonitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			
Diverticulitis			
subjects affected / exposed	2 / 1217 (0.16%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Appendicitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic abscess			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Cellulitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	2 / 903 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis infective			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	2 / 903 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Pneumonia			
subjects affected / exposed	1 / 1217 (0.08%)	1 / 226 (0.44%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 1217 (0.08%)	2 / 226 (0.88%)	0 / 903 (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
Staphylococcal abscess			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Staphylococcal skin infection			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal abscess			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
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 sinusitis			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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	2 / 1217 (0.16%)	0 / 226 (0.00%)	0 / 903 (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
Corona virus infection			
subjects affected / exposed	13 / 1217 (1.07%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	1 / 13	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 1217 (0.00%)	1 / 226 (0.44%)	0 / 903 (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
Pulmonary sepsis			
subjects affected / exposed	0 / 1217 (0.00%)	1 / 226 (0.44%)	0 / 903 (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
Pharyngitis streptococcal			
subjects affected / exposed	0 / 1217 (0.00%)	1 / 226 (0.44%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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			
Ketoacidosis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	1 / 903 (0.11%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (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
Diabetic ketoacidosis			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
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	Cohort B: EP BKZ Total	Cohort B: PSO BKZ Total	Cohort A: Group B BKZ 320 mg Q4W/Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 11 (45.45%)	7 / 45 (15.56%)	4 / 41 (9.76%)
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)			
Bladder transitional cell carcinoma			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 I			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 breast carcinoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma of colon			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid neoplasm			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tongue neoplasm benign			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 and/or oral cavity cancer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 lung			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatic adenoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 stage I			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 cell lung cancer metastatic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 cancer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 tract adenoma			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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
Small cell lung cancer			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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			
Aortic aneurysm			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Circulatory collapse			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm rupture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral artery embolism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Hip arthroplasty			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy on oral contraceptive			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Death			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stent-graft endoleak			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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
Oedema peripheral			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Cervical dysplasia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 polyp			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Genital haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Dyspnoea exertional			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngeal ulceration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pleurisy			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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
Pharyngeal ulceration			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Bipolar I disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol withdrawal syndrome			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug dependence			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax traumatic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 lumbar puncture syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaw fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 cardiomyopathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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
Cardiopulmonary failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systolic dysfunction			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 flutter			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulseless electrical activity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 ischaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic encephalopathy			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiplegic migraine			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Relapsing-remitting multiple sclerosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intercostal neuralgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spondylitic myelopathy			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Haemorrhagic anaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Microcytic anaemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic diathesis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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
Retinal detachment			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 hernia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 acute			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Anal prolapse			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 gastritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oroantral fistula			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 ulcerative			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Cholecystocholangitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 acute			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct obstruction			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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
Autoimmune hepatitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis atopic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erythrodermic psoriasis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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
Pustular psoriasis			

subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Acute kidney injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 failure			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 cyst			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal colic			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Hyperparathyroidism primary			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
Arthropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inclusion body myositis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Osteoarthritis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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 osteoarthritis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kyphosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendonitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 wall abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bursitis infective			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 skin infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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
Streptococcal abscess			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 sinusitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
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 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Corona virus infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (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
Metabolism and nutrition disorders			
Ketoacidosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			

subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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
Hyponatraemia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (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	Cohort B: GPP BKZ Total	Cohort A: Group B BKZ 320 mg Q8W	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 10 (20.00%)	5 / 51 (9.80%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder transitional cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage I			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive breast carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Colon cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma of colon			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid neoplasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tongue neoplasm benign			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lip and/or oral cavity cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain neoplasm			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostatic adenoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer stage I			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clear cell renal cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic bronchial carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer metastatic			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal tract adenoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small cell lung cancer			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Circulatory collapse			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral artery embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			

Hip arthroplasty subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy on oral contraceptive subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Death subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stent-graft endoleak subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Cervical dysplasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian cyst			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine prolapse			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Genital haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Laryngeal ulceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal ulceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Bipolar I disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug dependence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Meniscus injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post lumbar puncture syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			

subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Wolff-Parkinson-White syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive cardiomyopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			

subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systolic dysfunction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulseless electrical activity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral artery embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral ischaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Loss of consciousness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial pressure increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiplegic migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Relapsing-remitting multiple sclerosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intercostal neuralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylitic myelopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Haemorrhagic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microcytic anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic diathesis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal prolapse			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oroantral fistula			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticular perforation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ulcerative			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			

subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystocholangitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

<p> Dermatitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 0 / 10 (0.00%) 0 / 0 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Dermatitis atopic subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 0 / 10 (0.00%) 0 / 0 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Psoriasis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 0 / 10 (0.00%) 0 / 0 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Diabetic foot subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 0 / 10 (0.00%) 0 / 0 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Erythrodermic psoriasis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 0 / 10 (0.00%) 0 / 0 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Pustular psoriasis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 1 / 10 (10.00%) 0 / 1 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 0 / 10 (0.00%) 0 / 0 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Nephrolithiasis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all </p>	<p> 0 / 10 (0.00%) 0 / 0 0 / 0 </p>	<p> 0 / 51 (0.00%) 0 / 0 0 / 0 </p>	
<p> Renal failure </p>			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cyst			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperparathyroidism primary			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inappropriate antidiuretic hormone secretion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exostosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intervertebral disc protrusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inclusion body myositis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fibromyalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kyphosis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Diverticulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colonic abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal skin infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Streptococcal abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Corona virus infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Ketoacidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Cohort A: BKZ 320 mg Q8W	Cohort A: Group A BKZ 320 mg Q8W	Cohort A: BKZ 320 mg Q4W
Total subjects affected by non-serious adverse events subjects affected / exposed	771 / 1217 (63.35%)	97 / 226 (42.92%)	566 / 903 (62.68%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Acrochordon subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	2 / 903 (0.22%) 2
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	55 / 1217 (4.52%) 55	1 / 226 (0.44%) 1	33 / 903 (3.65%) 34
General disorders and administration site conditions Pyrexia subjects affected / exposed occurrences (all)	25 / 1217 (2.05%) 30	3 / 226 (1.33%) 3	8 / 903 (0.89%) 9
Peripheral swelling subjects affected / exposed occurrences (all)	8 / 1217 (0.66%) 9	0 / 226 (0.00%) 0	1 / 903 (0.11%) 1
Oedema peripheral subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 5	4 / 226 (1.77%) 4	0 / 903 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	3 / 903 (0.33%) 3
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	27 / 1217 (2.22%) 30	5 / 226 (2.21%) 5	21 / 903 (2.33%) 22
Oropharyngeal pain subjects affected / exposed occurrences (all)	16 / 1217 (1.31%) 16	0 / 226 (0.00%) 0	15 / 903 (1.66%) 15
Rhinitis allergic			

subjects affected / exposed occurrences (all)	13 / 1217 (1.07%) 13	1 / 226 (0.44%) 1	5 / 903 (0.55%) 5
Epistaxis subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Interstitial lung disease subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Investigations			
Gamma-glutamyltransferase increased subjects affected / exposed occurrences (all)	19 / 1217 (1.56%) 23	0 / 226 (0.00%) 0	6 / 903 (0.66%) 6
Hepatic enzyme increased subjects affected / exposed occurrences (all)	15 / 1217 (1.23%) 17	0 / 226 (0.00%) 0	7 / 903 (0.78%) 7
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	12 / 1217 (0.99%) 14	0 / 226 (0.00%) 0	5 / 903 (0.55%) 6
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	9 / 1217 (0.74%) 9	0 / 226 (0.00%) 0	5 / 903 (0.55%) 5
White blood cell count decreased subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 3	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Injury, poisoning and procedural complications			
Ligament sprain subjects affected / exposed occurrences (all)	10 / 1217 (0.82%) 10	2 / 226 (0.88%) 2	8 / 903 (0.89%) 8
Contusion subjects affected / exposed occurrences (all)	9 / 1217 (0.74%) 12	1 / 226 (0.44%) 1	5 / 903 (0.55%) 5
Arthropod bite subjects affected / exposed occurrences (all)	7 / 1217 (0.58%) 7	0 / 226 (0.00%) 0	6 / 903 (0.66%) 6
Skin abrasion			

subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 6	0 / 226 (0.00%) 0	4 / 903 (0.44%) 4
Bone contusion subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 2	0 / 226 (0.00%) 0	2 / 903 (0.22%) 2
Post-traumatic neck syndrome subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	2 / 903 (0.22%) 2
Eye injury subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Sternal fracture subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 2	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Cardiac disorders Cardiac failure chronic subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Cardiac hypertrophy subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	55 / 1217 (4.52%) 61	0 / 226 (0.00%) 0	20 / 903 (2.21%) 27
Dysgeusia subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	1 / 226 (0.44%) 1	0 / 903 (0.00%) 0
Blood and lymphatic system disorders Leukopenia subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	2 / 903 (0.22%) 2
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 5	0 / 226 (0.00%) 0	7 / 903 (0.78%) 7
Eye disorders			

Cataract			
subjects affected / exposed	12 / 1217 (0.99%)	2 / 226 (0.88%)	6 / 903 (0.66%)
occurrences (all)	14	3	6
Dry eye			
subjects affected / exposed	4 / 1217 (0.33%)	0 / 226 (0.00%)	4 / 903 (0.44%)
occurrences (all)	4	0	5
Conjunctivitis allergic			
subjects affected / exposed	8 / 1217 (0.66%)	1 / 226 (0.44%)	5 / 903 (0.55%)
occurrences (all)	8	1	5
Conjunctival haemorrhage			
subjects affected / exposed	1 / 1217 (0.08%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Gastrooesophageal reflux disease			
subjects affected / exposed	14 / 1217 (1.15%)	2 / 226 (0.88%)	17 / 903 (1.88%)
occurrences (all)	15	2	17
Diarrhoea			
subjects affected / exposed	24 / 1217 (1.97%)	2 / 226 (0.88%)	19 / 903 (2.10%)
occurrences (all)	27	2	20
Dental caries			
subjects affected / exposed	14 / 1217 (1.15%)	2 / 226 (0.88%)	7 / 903 (0.78%)
occurrences (all)	14	3	7
Abdominal pain			
subjects affected / exposed	11 / 1217 (0.90%)	0 / 226 (0.00%)	5 / 903 (0.55%)
occurrences (all)	12	0	5
Constipation			
subjects affected / exposed	6 / 1217 (0.49%)	1 / 226 (0.44%)	4 / 903 (0.44%)
occurrences (all)	6	1	4
Abdominal pain upper			
subjects affected / exposed	8 / 1217 (0.66%)	0 / 226 (0.00%)	5 / 903 (0.55%)
occurrences (all)	8	0	7
Nausea			
subjects affected / exposed	11 / 1217 (0.90%)	1 / 226 (0.44%)	4 / 903 (0.44%)
occurrences (all)	13	1	4
Abdominal distension			

subjects affected / exposed occurrences (all)	4 / 1217 (0.33%) 4	0 / 226 (0.00%) 0	3 / 903 (0.33%) 3
Gastritis subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 5	1 / 226 (0.44%) 1	5 / 903 (0.55%) 5
Stomatitis subjects affected / exposed occurrences (all)	3 / 1217 (0.25%) 3	0 / 226 (0.00%) 0	3 / 903 (0.33%) 3
Haemorrhoids subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 2	0 / 226 (0.00%) 0	5 / 903 (0.55%) 5
Chronic gastritis subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 2	0 / 226 (0.00%) 0	3 / 903 (0.33%) 3
Glossitis subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 2	0 / 226 (0.00%) 0	2 / 903 (0.22%) 2
Haemorrhoidal haemorrhage subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Coating in mouth subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	1 / 903 (0.11%) 1
Hepatobiliary disorders Drug-induced liver injury subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Hepatic function abnormal subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Hepatic steatosis subjects affected / exposed occurrences (all)	10 / 1217 (0.82%) 10	1 / 226 (0.44%) 1	4 / 903 (0.44%) 4
Skin and subcutaneous tissue disorders Psoriasis			

subjects affected / exposed	44 / 1217 (3.62%)	3 / 226 (1.33%)	16 / 903 (1.77%)
occurrences (all)	52	4	18
Dermatitis contact			
subjects affected / exposed	34 / 1217 (2.79%)	2 / 226 (0.88%)	25 / 903 (2.77%)
occurrences (all)	38	2	32
Eczema			
subjects affected / exposed	30 / 1217 (2.47%)	1 / 226 (0.44%)	17 / 903 (1.88%)
occurrences (all)	42	1	21
Seborrhoeic dermatitis			
subjects affected / exposed	15 / 1217 (1.23%)	1 / 226 (0.44%)	10 / 903 (1.11%)
occurrences (all)	15	1	11
Urticaria			
subjects affected / exposed	13 / 1217 (1.07%)	0 / 226 (0.00%)	6 / 903 (0.66%)
occurrences (all)	13	0	7
Eczema asteatotic			
subjects affected / exposed	14 / 1217 (1.15%)	0 / 226 (0.00%)	5 / 903 (0.55%)
occurrences (all)	14	0	5
Rash			
subjects affected / exposed	6 / 1217 (0.49%)	1 / 226 (0.44%)	3 / 903 (0.33%)
occurrences (all)	7	1	3
Dry skin			
subjects affected / exposed	3 / 1217 (0.25%)	1 / 226 (0.44%)	6 / 903 (0.66%)
occurrences (all)	3	1	7
Acne			
subjects affected / exposed	9 / 1217 (0.74%)	0 / 226 (0.00%)	9 / 903 (1.00%)
occurrences (all)	9	0	9
Dyshidrotic eczema			
subjects affected / exposed	6 / 1217 (0.49%)	2 / 226 (0.88%)	2 / 903 (0.22%)
occurrences (all)	7	2	2
Dermal cyst			
subjects affected / exposed	5 / 1217 (0.41%)	0 / 226 (0.00%)	2 / 903 (0.22%)
occurrences (all)	5	0	2
Hyperkeratosis			
subjects affected / exposed	1 / 1217 (0.08%)	1 / 226 (0.44%)	3 / 903 (0.33%)
occurrences (all)	2	1	3
Pustular psoriasis			

subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	1 / 903 (0.11%) 1
Skin ulcer subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	1 / 903 (0.11%) 1
Milia subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Erythrodermic psoriasis subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Renal and urinary disorders Renal impairment subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	48 / 1217 (3.94%) 55	0 / 226 (0.00%) 0	19 / 903 (2.10%) 22
Back pain subjects affected / exposed occurrences (all)	28 / 1217 (2.30%) 31	3 / 226 (1.33%) 3	23 / 903 (2.55%) 24
Psoriatic arthropathy subjects affected / exposed occurrences (all)	26 / 1217 (2.14%) 27	5 / 226 (2.21%) 5	5 / 903 (0.55%) 5
Osteoarthritis subjects affected / exposed occurrences (all)	9 / 1217 (0.74%) 10	0 / 226 (0.00%) 0	9 / 903 (1.00%) 11
Tendonitis subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 7	0 / 226 (0.00%) 0	7 / 903 (0.78%) 8
Bursitis			

subjects affected / exposed occurrences (all)	7 / 1217 (0.58%) 8	0 / 226 (0.00%) 0	3 / 903 (0.33%) 3
Arthritis subjects affected / exposed occurrences (all)	7 / 1217 (0.58%) 10	0 / 226 (0.00%) 0	2 / 903 (0.22%) 2
Muscular weakness subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 2	0 / 226 (0.00%) 0	2 / 903 (0.22%) 2
Myositis subjects affected / exposed occurrences (all)	0 / 1217 (0.00%) 0	0 / 226 (0.00%) 0	0 / 903 (0.00%) 0
Plantar fasciitis subjects affected / exposed occurrences (all)	2 / 1217 (0.16%) 2	1 / 226 (0.44%) 1	1 / 903 (0.11%) 1
Infections and infestations			
Oral candidiasis subjects affected / exposed occurrences (all)	127 / 1217 (10.44%) 238	13 / 226 (5.75%) 18	145 / 903 (16.06%) 234
Nasopharyngitis subjects affected / exposed occurrences (all)	152 / 1217 (12.49%) 223	14 / 226 (6.19%) 15	174 / 903 (19.27%) 230
Corona virus infection subjects affected / exposed occurrences (all)	174 / 1217 (14.30%) 187	34 / 226 (15.04%) 35	18 / 903 (1.99%) 18
Upper respiratory tract infection subjects affected / exposed occurrences (all)	97 / 1217 (7.97%) 127	12 / 226 (5.31%) 14	74 / 903 (8.19%) 85
Urinary tract infection subjects affected / exposed occurrences (all)	58 / 1217 (4.77%) 79	6 / 226 (2.65%) 8	49 / 903 (5.43%) 72
Folliculitis subjects affected / exposed occurrences (all)	24 / 1217 (1.97%) 30	1 / 226 (0.44%) 1	35 / 903 (3.88%) 43
Pharyngitis			

subjects affected / exposed	27 / 1217 (2.22%)	0 / 226 (0.00%)	19 / 903 (2.10%)
occurrences (all)	28	0	22
Conjunctivitis			
subjects affected / exposed	20 / 1217 (1.64%)	1 / 226 (0.44%)	25 / 903 (2.77%)
occurrences (all)	22	1	30
Oral herpes			
subjects affected / exposed	15 / 1217 (1.23%)	0 / 226 (0.00%)	16 / 903 (1.77%)
occurrences (all)	19	0	18
Otitis externa			
subjects affected / exposed	17 / 1217 (1.40%)	1 / 226 (0.44%)	13 / 903 (1.44%)
occurrences (all)	19	1	15
Angular cheilitis			
subjects affected / exposed	14 / 1217 (1.15%)	0 / 226 (0.00%)	14 / 903 (1.55%)
occurrences (all)	15	0	18
Tinea pedis			
subjects affected / exposed	16 / 1217 (1.31%)	0 / 226 (0.00%)	12 / 903 (1.33%)
occurrences (all)	16	0	13
Influenza			
subjects affected / exposed	12 / 1217 (0.99%)	1 / 226 (0.44%)	9 / 903 (1.00%)
occurrences (all)	13	1	11
Cellulitis			
subjects affected / exposed	10 / 1217 (0.82%)	0 / 226 (0.00%)	7 / 903 (0.78%)
occurrences (all)	11	0	8
Cystitis			
subjects affected / exposed	9 / 1217 (0.74%)	2 / 226 (0.88%)	4 / 903 (0.44%)
occurrences (all)	11	2	5
Skin bacterial infection			
subjects affected / exposed	3 / 1217 (0.25%)	0 / 226 (0.00%)	5 / 903 (0.55%)
occurrences (all)	3	0	5
Erysipelas			
subjects affected / exposed	3 / 1217 (0.25%)	1 / 226 (0.44%)	4 / 903 (0.44%)
occurrences (all)	4	1	5
Wound infection staphylococcal			
subjects affected / exposed	0 / 1217 (0.00%)	0 / 226 (0.00%)	0 / 903 (0.00%)
occurrences (all)	0	0	0
Genital candidiasis			

subjects affected / exposed occurrences (all)	1 / 1217 (0.08%) 1	0 / 226 (0.00%) 0	1 / 903 (0.11%) 1
Tinea cruris subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 5	0 / 226 (0.00%) 0	1 / 903 (0.11%) 1
Paronychia subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 7	1 / 226 (0.44%) 1	2 / 903 (0.22%) 3
Metabolism and nutrition disorders			
Hypercholesterolaemia subjects affected / exposed occurrences (all)	11 / 1217 (0.90%) 11	0 / 226 (0.00%) 0	9 / 903 (1.00%) 9
Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	13 / 1217 (1.07%) 14	1 / 226 (0.44%) 1	8 / 903 (0.89%) 8
Diabetes mellitus subjects affected / exposed occurrences (all)	12 / 1217 (0.99%) 12	0 / 226 (0.00%) 0	6 / 903 (0.66%) 6
Hyperlipidaemia subjects affected / exposed occurrences (all)	7 / 1217 (0.58%) 7	0 / 226 (0.00%) 0	4 / 903 (0.44%) 4
Hyperuricaemia subjects affected / exposed occurrences (all)	5 / 1217 (0.41%) 5	0 / 226 (0.00%) 0	1 / 903 (0.11%) 1

Non-serious adverse events	Cohort B: EP BKZ Total	Cohort B: PSO BKZ Total	Cohort A: Group B BKZ 320 mg Q4W/Q8W
Total subjects affected by non-serious adverse events subjects affected / exposed	11 / 11 (100.00%)	43 / 45 (95.56%)	21 / 41 (51.22%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Acrochordon subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 45 (2.22%) 1	0 / 41 (0.00%) 0
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	2 / 45 (4.44%) 2	1 / 41 (2.44%) 1

General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 11 (9.09%)	10 / 45 (22.22%)	0 / 41 (0.00%)
occurrences (all)	1	11	0
Peripheral swelling			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	1 / 11 (9.09%)	2 / 45 (4.44%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Malaise			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 11 (9.09%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	1	2	0
Oropharyngeal pain			
subjects affected / exposed	1 / 11 (9.09%)	3 / 45 (6.67%)	0 / 41 (0.00%)
occurrences (all)	1	3	0
Rhinitis allergic			
subjects affected / exposed	0 / 11 (0.00%)	3 / 45 (6.67%)	1 / 41 (2.44%)
occurrences (all)	0	3	1
Epistaxis			
subjects affected / exposed	1 / 11 (9.09%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Interstitial lung disease			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Hepatic enzyme increased			

subjects affected / exposed	1 / 11 (9.09%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	2 / 45 (4.44%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 11 (9.09%)	3 / 45 (6.67%)	0 / 41 (0.00%)
occurrences (all)	1	3	0
Arthropod bite			
subjects affected / exposed	1 / 11 (9.09%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Skin abrasion			
subjects affected / exposed	0 / 11 (0.00%)	3 / 45 (6.67%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
Bone contusion			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Eye injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Sternal fracture			

subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Cardiac disorders			
Cardiac failure chronic subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Cardiac hypertrophy subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	4 / 45 (8.89%) 4	0 / 41 (0.00%) 0
Dysgeusia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	3 / 45 (6.67%) 3	0 / 41 (0.00%) 0
Blood and lymphatic system disorders			
Leukopenia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 45 (4.44%) 3	0 / 41 (0.00%) 0
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	2 / 11 (18.18%) 2	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Eye disorders			
Cataract subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 45 (4.44%) 2	0 / 41 (0.00%) 0
Dry eye subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Conjunctivitis allergic subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	2 / 45 (4.44%) 2	0 / 41 (0.00%) 0
Conjunctival haemorrhage subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0

Gastrointestinal disorders			
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	2 / 41 (4.88%)
occurrences (all)	0	1	2
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)	7 / 45 (15.56%)	0 / 41 (0.00%)
occurrences (all)	0	8	0
Dental caries			
subjects affected / exposed	0 / 11 (0.00%)	7 / 45 (15.56%)	1 / 41 (2.44%)
occurrences (all)	0	8	1
Abdominal pain			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 11 (0.00%)	3 / 45 (6.67%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
Abdominal pain upper			
subjects affected / exposed	1 / 11 (9.09%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	1 / 11 (9.09%)	3 / 45 (6.67%)	0 / 41 (0.00%)
occurrences (all)	1	7	0
Haemorrhoids			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 45 (4.44%) 2	0 / 41 (0.00%) 0
Glossitis			
subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	3 / 45 (6.67%) 5	0 / 41 (0.00%) 0
Haemorrhoidal haemorrhage			
subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 45 (2.22%) 1	0 / 41 (0.00%) 0
Coating in mouth			
subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Hepatic function abnormal			
subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 2	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Hepatic steatosis			
subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	4 / 45 (8.89%) 4	0 / 41 (0.00%) 0
Dermatitis contact			
subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	6 / 45 (13.33%) 9	4 / 41 (9.76%) 5
Eczema			
subjects affected / exposed occurrences (all)	3 / 11 (27.27%) 3	15 / 45 (33.33%) 28	0 / 41 (0.00%) 0
Seborrhoeic dermatitis			
subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 45 (2.22%) 3	1 / 41 (2.44%) 1
Urticaria			

subjects affected / exposed	0 / 11 (0.00%)	2 / 45 (4.44%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Eczema asteatotic			
subjects affected / exposed	1 / 11 (9.09%)	5 / 45 (11.11%)	0 / 41 (0.00%)
occurrences (all)	1	5	0
Rash			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Acne			
subjects affected / exposed	0 / 11 (0.00%)	2 / 45 (4.44%)	0 / 41 (0.00%)
occurrences (all)	0	2	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Dermal cyst			
subjects affected / exposed	1 / 11 (9.09%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Hyperkeratosis			
subjects affected / exposed	0 / 11 (0.00%)	3 / 45 (6.67%)	0 / 41 (0.00%)
occurrences (all)	0	3	0
Pustular psoriasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	1 / 41 (2.44%)
occurrences (all)	3	0	1
Milia			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Erythrodermic psoriasis			
subjects affected / exposed	2 / 11 (18.18%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			

Renal impairment subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	4 / 45 (8.89%) 6	1 / 41 (2.44%) 1
Back pain subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	2 / 45 (4.44%) 2	0 / 41 (0.00%) 0
Psoriatic arthropathy subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 45 (2.22%) 1	1 / 41 (2.44%) 1
Osteoarthritis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 45 (2.22%) 1	0 / 41 (0.00%) 0
Tendonitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 45 (2.22%) 1	0 / 41 (0.00%) 0
Bursitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Muscular weakness subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Myositis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Plantar fasciitis			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Infections and infestations			
Oral candidiasis subjects affected / exposed occurrences (all)	4 / 11 (36.36%) 4	11 / 45 (24.44%) 18	6 / 41 (14.63%) 6
Nasopharyngitis subjects affected / exposed occurrences (all)	7 / 11 (63.64%) 9	19 / 45 (42.22%) 25	1 / 41 (2.44%) 1
Corona virus infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 45 (0.00%) 0	8 / 41 (19.51%) 8
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 45 (4.44%) 2	0 / 41 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 45 (0.00%) 0	0 / 41 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 2	7 / 45 (15.56%) 11	1 / 41 (2.44%) 2
Pharyngitis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	3 / 45 (6.67%) 3	1 / 41 (2.44%) 1
Conjunctivitis subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	1 / 45 (2.22%) 1	1 / 41 (2.44%) 1
Oral herpes subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 2	1 / 45 (2.22%) 1	0 / 41 (0.00%) 0
Otitis externa subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	5 / 45 (11.11%) 7	1 / 41 (2.44%) 3
Angular cheilitis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	3 / 45 (6.67%) 3	0 / 41 (0.00%) 0

Tinea pedis			
subjects affected / exposed	1 / 11 (9.09%)	5 / 45 (11.11%)	0 / 41 (0.00%)
occurrences (all)	1	5	0
Influenza			
subjects affected / exposed	1 / 11 (9.09%)	4 / 45 (8.89%)	1 / 41 (2.44%)
occurrences (all)	1	4	1
Cellulitis			
subjects affected / exposed	2 / 11 (18.18%)	2 / 45 (4.44%)	1 / 41 (2.44%)
occurrences (all)	2	2	1
Cystitis			
subjects affected / exposed	1 / 11 (9.09%)	2 / 45 (4.44%)	0 / 41 (0.00%)
occurrences (all)	1	3	0
Skin bacterial infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Erysipelas			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Wound infection staphylococcal			
subjects affected / exposed	1 / 11 (9.09%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Genital candidiasis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 45 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	1 / 11 (9.09%)	2 / 45 (4.44%)	1 / 41 (2.44%)
occurrences (all)	1	3	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Type 2 diabetes mellitus			

subjects affected / exposed	1 / 11 (9.09%)	3 / 45 (6.67%)	0 / 41 (0.00%)
occurrences (all)	1	3	0
Diabetes mellitus			
subjects affected / exposed	1 / 11 (9.09%)	1 / 45 (2.22%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Hyperlipidaemia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 45 (2.22%)	1 / 41 (2.44%)
occurrences (all)	0	1	1
Hyperuricaemia			
subjects affected / exposed	0 / 11 (0.00%)	2 / 45 (4.44%)	0 / 41 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Cohort B: GPP BKZ Total	Cohort A: Group B BKZ 320 mg Q8W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 10 (90.00%)	16 / 51 (31.37%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acrochordon			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	3 / 10 (30.00%)	0 / 51 (0.00%)	
occurrences (all)	4	0	
Peripheral swelling			
subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Interstitial lung disease			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Investigations			
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Alanine aminotransferase increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 51 (0.00%)	
occurrences (all)	2	0	
White blood cell count decreased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			

Ligament sprain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Arthropod bite			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Skin abrasion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Bone contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Eye injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Sternal fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Cardiac failure chronic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Cardiac hypertrophy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Blood and lymphatic system disorders Leukopenia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Ear and labyrinth disorders Vertigo subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Eye disorders Cataract subjects affected / exposed occurrences (all) Dry eye subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all) Conjunctival haemorrhage subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1 1 / 10 (10.00%) 1 1 / 10 (10.00%) 1 0 / 10 (0.00%) 0	0 / 51 (0.00%) 0 0 / 51 (0.00%) 0 0 / 51 (0.00%) 0 0 / 51 (0.00%) 0	
Gastrointestinal disorders Gastrooesophageal reflux disease subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Dental caries subjects affected / exposed occurrences (all) Abdominal pain subjects affected / exposed occurrences (all) Constipation	1 / 10 (10.00%) 1 2 / 10 (20.00%) 2 1 / 10 (10.00%) 1 1 / 10 (10.00%) 1 1	0 / 51 (0.00%) 0 0 / 51 (0.00%) 0 0 / 51 (0.00%) 0 0 / 51 (0.00%) 0	

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Nausea subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Abdominal distension subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Gastritis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Stomatitis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Haemorrhoids subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Chronic gastritis subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	0 / 51 (0.00%) 0	
Glossitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Haemorrhoidal haemorrhage subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Coating in mouth subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Hepatobiliary disorders Drug-induced liver injury subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	

Hepatic function abnormal subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Hepatic steatosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Skin and subcutaneous tissue disorders			
Psoriasis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Dermatitis contact subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	2 / 51 (3.92%) 2	
Eczema subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Seborrhoeic dermatitis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Urticaria subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Eczema asteatotic subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Rash subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	0 / 51 (0.00%) 0	
Dry skin subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Acne subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 3	0 / 51 (0.00%) 0	
Dyshidrotic eczema			

subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Dermal cyst subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	1 / 51 (1.96%) 1	
Hyperkeratosis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Pustular psoriasis subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Skin ulcer subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Milia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Erythrodermic psoriasis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Renal and urinary disorders Renal impairment subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Endocrine disorders Adrenal insufficiency subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 51 (0.00%) 0	
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 1	0 / 51 (0.00%) 0	
Back pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	1 / 51 (1.96%) 1	
Psoriatic arthropathy			

subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Tendonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Bursitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Myositis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Plantar fasciitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Oral candidiasis			
subjects affected / exposed	2 / 10 (20.00%)	3 / 51 (5.88%)	
occurrences (all)	2	5	
Nasopharyngitis			
subjects affected / exposed	2 / 10 (20.00%)	1 / 51 (1.96%)	
occurrences (all)	2	1	
Corona virus infection			
subjects affected / exposed	0 / 10 (0.00%)	3 / 51 (5.88%)	
occurrences (all)	0	3	
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences (all)	0	1	

Urinary tract infection		
subjects affected / exposed	0 / 10 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	2
Folliculitis		
subjects affected / exposed	1 / 10 (10.00%)	1 / 51 (1.96%)
occurrences (all)	1	1
Pharyngitis		
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)
occurrences (all)	1	0
Conjunctivitis		
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0
Oral herpes		
subjects affected / exposed	1 / 10 (10.00%)	1 / 51 (1.96%)
occurrences (all)	3	1
Otitis externa		
subjects affected / exposed	1 / 10 (10.00%)	1 / 51 (1.96%)
occurrences (all)	2	1
Angular cheilitis		
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0
Tinea pedis		
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0
Influenza		
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)
occurrences (all)	1	0
Cellulitis		
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0
Cystitis		
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0
Skin bacterial infection		
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)
occurrences (all)	1	0

Erysipelas			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Wound infection staphylococcal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Genital candidiasis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Tinea cruris			
subjects affected / exposed	1 / 10 (10.00%)	1 / 51 (1.96%)	
occurrences (all)	1	1	
Paronychia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 51 (0.00%)	
occurrences (all)	0	0	
Diabetes mellitus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 51 (1.96%)	
occurrences (all)	0	1	
Hyperlipidaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 51 (1.96%)	
occurrences (all)	1	1	
Hyperuricaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 51 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 January 2019	Protocol Amendment 1 (dated 16 Jan 2019) implemented the following key modifications to the original protocol: 1. Extended the study duration for an additional 2 years. 2. Included guidance to allow study participants the option to self-inject IMP at home after Week 48. 3. Modified guidance to the Investigator regarding changing a study participant's dosing interval from 320 mg Q4W to 320 mg Q8W if PASI90 was achieved at Week 24 (clarifying that this was optional); also, added a requirement that a study participant's dosing interval changed from 320 mg Q4W to 320 mg Q8W (default) if PASI90 was achieved at Week 48 unless, based on medical judgement, the Investigator decided differently. 4. Provided rationale as to why study participants who received bimekizumab 320 mg Q4W, but did not achieve PASI90 in the feeder study, continued receiving bimekizumab 320mg Q4W in PS0014 (requested by the Medicines and Healthcare products Regulatory Agency). 5. Amended Inclusion Criterion to add contraceptive measures according to the feeder studies PS0009 and PS0013 (requested by the Medicines and Healthcare products Regulatory Agency). 6. Amended Exclusion Criterion to clarify that the Investigator had the ultimate decision regarding whether a study participant with an ongoing SAE, or a history of serious infections in the feeder study, continued receiving bimekizumab in PS0014 (requested by the Medicines and Healthcare products Regulatory Agency).
16 January 2019	Continuation to Protocol Amendment 1: 7. Amended Exclusion Criterion to clarify that study participants who had a positive or indeterminate IGRA test result in a feeder study were excluded from PS0014 unless they were appropriately evaluated and treated. 8. Updated the lists of efficacy, safety, and PK variables; added the Treatment Satisfaction Questionnaire for Medication (TSQM-9) to the study as an "other" efficacy variable; and updated the corresponding description of statistical methods. 9. Changed the pregnancy testing assessment to urine pregnancy testing at all study visits. 10. Updated Protocol Section (Evaluation of potential drug-induced liver injury [PDILI]) for improved clarity. 11. Added plans for interim analyses at Week 24 and Week 48.
09 June 2020	Protocol Amendment 2 (dated 09 Jun 2020) implemented the following key modifications: 1. Changed the dose regimen at Week 48 (or at the next scheduled clinic visit if the study participant had already completed the Week 48 Visit) from bimekizumab 320 mg Q4W to bimekizumab 320 mg Q8W, based on pooled data from the Phase 3 studies (PS0008, PS0009, and PS0013), which demonstrated that during the Maintenance Period, bimekizumab 320 mg Q8W provided essentially the same efficacy as bimekizumab 320 mg Q4W (note: Protocol Amendment 3 included modifications/corrections to the description of study procedures to align with the changes made in Protocol Amendment 2). 2. Corrected the omission of Canada from the list of countries where the PS0014 substudy evaluating the safe and effective use of self-injecting device presentations was conducted, ensuring consistency with the substudy protocol (DV0002). 3. Added provision for collecting a concurrent sample for central laboratory testing if laboratory tests were performed locally. 4. Aligned text pertaining to secondary efficacy variables, other safety variables, other efficacy variables, and statistical analyses with the Statistical Analysis Plan (SAP).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported