



Clinical trial results:

A Phase 3, Multicenter, Randomized, Double-blind, Placebo and Active Comparator- Controlled Study Evaluating the Efficacy and Safety of Guselkumab for the Treatment of Subjects with Moderate to Severe Plaque-type Psoriasis with Randomized Withdrawal and Retreatment Summary

EudraCT number	2014-000720-18
Trial protocol	DE CZ PL ES
Global end of trial date	01 July 2020

Results information

Result version number	v1 (current)
This version publication date	16 July 2021
First version publication date	16 July 2021

Trial information

Trial identification

Sponsor protocol code	CNT01959PSO3002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02207244
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Pharmaceutical
Sponsor organisation address	1400 McKean Rd., Spring House, United States,
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.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	01 July 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	01 July 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this study were to evaluate the efficacy, safety, and tolerability of guselkumab in the treatment of subjects with moderate to severe plaque-type psoriasis.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. The safety and tolerability of guselkumab and adalimumab were monitored by collecting information on adverse events (AEs), including injection-site reactions (ISRs) and allergic reactions, clinical laboratory tests, physical examinations, vital signs, electrocardiograms (ECGs), concomitant medication review, and early detection of active tuberculosis (TB).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 November 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 51
Country: Number of subjects enrolled	Canada: 130
Country: Number of subjects enrolled	Korea, Republic of: 98
Country: Number of subjects enrolled	Russian Federation: 100
Country: Number of subjects enrolled	United States: 190
Country: Number of subjects enrolled	Germany: 84
Country: Number of subjects enrolled	Poland: 265
Country: Number of subjects enrolled	Spain: 43
Country: Number of subjects enrolled	Czechia: 31
Worldwide total number of subjects	992
EEA total number of subjects	423

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	949
From 65 to 84 years	43
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 1279 subjects were screened. Of these 1279, 992 subjects were randomized.

Period 1

Period 1 title	Placebo Controlled Period: Week 0 - 16
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo (Week 0 - 16)

Arm description:

Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP).

Arm type	Placebo
Investigational medicinal product name	Placebo (for guselkumab)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection in pre-filled syringe, Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo matching to guselkumab was administered subcutaneously at Weeks 0, 4 and 12 in PCP.

Investigational medicinal product name	Placebo (for adalimumab)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo matching to adalimumab was administered subcutaneously (2 doses) at Week 0 followed by single subcutaneous dose thereafter through Week 15 in PCP.

Arm title	Guselkumab 100 mg (Week 0 - 16)
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Arm description:

Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Weeks 0, 4, and 12.

Arm title	Adalimumab (Week 0 - 16)
Arm description: Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP.	
Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab 80 mg was administered subcutaneously (2 doses) at Week 0 followed by single subcutaneous dose of adalimumab 40 mg at Week 1 and thereafter through Week 15.

Number of subjects in period 1	Placebo (Week 0 - 16)	Guselkumab 100 mg (Week 0 - 16)	Adalimumab (Week 0 - 16)
Started	248	496	248
Completed	233	478	237
Not completed	15	18	11
Consent withdrawn by subject	7	1	-
Adverse event, non-fatal	2	9	4
Unspecified	-	2	2
Lost to follow-up	1	3	2
Protocol deviation	1	3	1
Lack of efficacy	4	-	2

Period 2

Period 2 title	Placebo crossover and ACP: Week 16 - 28
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo then Guselkumab 100 mg (Week 16 - 28)
Arm description: Subjects who started receiving placebo in the first period were crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21, and 23 during the active comparator controlled period (ACP).	
Arm type	Placebo

Investigational medicinal product name	Placebo (for adalimumab)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo matching to adalimumab was administered subcutaneously at Weeks 17, 19, 21, 23, and q2w in active controlled period.

Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to subjects receiving matching placebo in PCP and crossed over to receive guselkumab in ACP.

Arm title	Guselkumab 100 mg (Week 16 - 28)
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Arm description:

Subjects who started receiving guselkumab in the first period, received placebo matched to guselkumab SC injection at Week 16 followed by guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously q8w in ACP to subjects initially receiving guselkumab 100 mg in PCP.

Arm title	Adalimumab (Week 16 - 28)
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Arm description:

Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) every 2 weeks (q2w) from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab 40 mg was administered to subcutaneously q2w in ACP to subjects who were initially receiving adalimumab in PCP.

Number of subjects in period 2	Placebo then Guselkumab 100 mg (Week 16 - 28)	Guselkumab 100 mg (Week 16 - 28)	Adalimumab (Week 16 - 28)
Started	233	478	237
Completed	227	470	228
Not completed	6	8	9
Consent withdrawn by subject	3	3	2
Adverse event, non-fatal	-	3	2
Unspecified	1	-	-
Lost to follow-up	1	2	2
Protocol deviation	1	-	1
Lack of efficacy	-	-	2

Period 3

Period 3 title	Withdrawal and Re-treatment: Week 28-72
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo then Guselkumab 100 mg (Week 28 - 72)

Arm description:

Subjects assigned to the placebo, then guselkumab arm through Week 28 were assessed for psoriasis area and severity index (PASI) 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and then every 8 weeks (q8w) thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders at Week 28 received placebo matched to guselkumab SC injection at Week 28 and every 4 weeks (q4w) thereafter through Week 72 or until loss of greater than or equal to (\geq) 50 percentage (%) in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.

Arm type	Placebo
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to PASI 90 non-responders at Week 28 and then q8w thereafter through Week 72.

Investigational medicinal product name	Placebo (for guselkumab)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo matching to guselkumab was administered subcutaneously to PASI 90 non-responders at Week 32 and then q8w through Week 72 whereas placebo matching to guselkumab was administered subcutaneously to PASI 90 responders at Week 28 and q4w thereafter through Week 72 or until loss of $\geq 50\%$ the improvement in PASI.

Arm title	Guselkumab 100 mg (Week 28 - 72)
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Arm description:

Subjects assigned to the guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders were re-randomized to either guselkumab or placebo. Subjects re-randomized to guselkumab, received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32 and then q8w through Week 72. Subjects re-randomized to placebo, received placebo matched to guselkumab SC injection q4w through Week 72 or until loss of $\geq 50\%$ in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to PASI 90 non-responders at Week 28 and q8w thereafter through Week 72 whereas PASI 90 responders were re-randomized to guselkumab through Week 72.

Arm title	Adalimumab then Guselkumab 100 mg (Week 28 - 72)
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Arm description:

Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 36 and 44. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of $\geq 50\%$ in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were treated with guselkumab.

Arm type	Active comparator
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously to PASI 90 non-responders at Week 28 and 32 and q8w thereafter through Week 72.

Arm title	Adalimumab (After ACP)
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Arm description:

Subjects who received adalimumab 80 mg at Week 0 and adalimumab 40 mg at Week 1 and every other week through Week 23 were assessed for PASI 90 response at Week 28. PASI 90 responders who did not crossover to guselkumab upon loss of $\geq 50\%$ in the improvement in PASI and did not continue any treatment at Week 28 are reported in this arm.

Arm type	Active comparator
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Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab 40 mg was administered subcutaneously to subjects through Week 23.

Number of subjects in period 3	Placebo then Guselkumab 100 mg (Week 28 - 72)	Guselkumab 100 mg (Week 28 - 72)	Adalimumab then Guselkumab 100 mg (Week 28 - 72)
Started	227	470	220
Nonresponders	80 ^[1]	95 ^[2]	112 ^[3]
Responders at Week (Wk) 28	0 ^[4]	375 ^[5]	0 ^[6]
Responders at Wk 28, withdrawn treatment	147 ^[7]	0 ^[8]	108 ^[9]
Completed	213	443	211
Not completed	14	27	9
Consent withdrawn by subject	2	7	2
Adverse event, non-fatal	1	5	3
Pregnancy	-	2	-
Unspecified	-	2	-
Subjects not retreated with guselkumab	8	-	-
Lost to follow-up	2	7	-
Lack of efficacy	1	3	2
Protocol deviation	-	1	1
Noncompliance	-	-	1

Number of subjects in period 3	Adalimumab (After ACP)
Started	8
Nonresponders	0
Responders at Week (Wk) 28	0
Responders at Wk 28, withdrawn treatment	0
Completed	0
Not completed	8
Consent withdrawn by subject	2
Adverse event, non-fatal	2
Pregnancy	-
Unspecified	-
Subjects not retreated with guselkumab	-
Lost to follow-up	2

Lack of efficacy	2
Protocol deviation	-
Noncompliance	-

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: There were only specified number of subjects in each arm of each milestone.

Period 4

Period 4 title	Open-label Guselkumab: Week 72-264
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Guselkumab Combined

Arm description:

All subjects who received guselkumab 100 mg subcutaneously q8w at Week 76 and thereafter through Week 252.

Arm type	Experimental
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Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use
Dosage and administration details:	
Guselkumab 100 mg was administered subcutaneously at Week 76 and then q8w through Week 252.	
Arm title	Adalimumab then Guselkumab 100 mg (Week 72 - 264)

Arm description:

All subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

Arm type	Experimental
Investigational medicinal product name	Guselkumab
Investigational medicinal product code	
Other name	CNT01959
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Guselkumab 100 mg was administered subcutaneously at Week 76 and then q8w through Week 252.

Number of subjects in period 4	Guselkumab Combined	Adalimumab then Guselkumab 100 mg (Week 72 - 264)
Started	656	211
Completed	554	173
Not completed	102	38
Adverse event, serious fatal	1	1
Consent withdrawn by subject	30	10
Adverse event, non-fatal	21	12
Pregnancy	2	-
Unspecified	19	8
Lost to follow-up	26	5
Lack of efficacy	3	2

Baseline characteristics

Reporting groups

Reporting group title	Placebo (Week 0 - 16)
Reporting group description: Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP).	
Reporting group title	Guselkumab 100 mg (Week 0 - 16)
Reporting group description: Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP.	
Reporting group title	Adalimumab (Week 0 - 16)
Reporting group description: Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP.	

Reporting group values	Placebo (Week 0 - 16)	Guselkumab 100 mg (Week 0 - 16)	Adalimumab (Week 0 - 16)
Number of subjects	248	496	248
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	239	473	237
From 65 to 84 years	9	23	11
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	43.3	43.7	43.2
standard deviation	± 12.38	± 12.23	± 11.92
Title for Gender Units: subjects			
Female	75	147	78
Male	173	349	170

Reporting group values	Total		
Number of subjects	992		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	949		
From 65 to 84 years	43		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			

standard deviation	-		
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Title for Gender			
Units: subjects			
Female	300		
Male	692		

End points

End points reporting groups

Reporting group title	Placebo (Week 0 - 16)
Reporting group description: Subjects received placebo matched to guselkumab subcutaneous (SC) injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP).	
Reporting group title	Guselkumab 100 mg (Week 0 - 16)
Reporting group description: Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP.	
Reporting group title	Adalimumab (Week 0 - 16)
Reporting group description: Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP.	
Reporting group title	Placebo then Guselkumab 100 mg (Week 16 - 28)
Reporting group description: Subjects who started receiving placebo in the first period were crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21, and 23 during the active comparator controlled period (ACP).	
Reporting group title	Guselkumab 100 mg (Week 16 - 28)
Reporting group description: Subjects who started receiving guselkumab in the first period, received placebo matched to guselkumab SC injection at Week 16 followed by guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.	
Reporting group title	Adalimumab (Week 16 - 28)
Reporting group description: Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) every 2 weeks (q2w) from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.	
Reporting group title	Placebo then Guselkumab 100 mg (Week 28 - 72)
Reporting group description: Subjects assigned to the placebo, then guselkumab arm through Week 28 were assessed for psoriasis area and severity index (PASI) 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and then every 8 weeks (q8w) thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders at Week 28 received placebo matched to guselkumab SC injection at Week 28 and every 4 weeks (q4w) thereafter through Week 72 or until loss of greater than or equal to (\geq) 50 percentage (%) in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.	
Reporting group title	Guselkumab 100 mg (Week 28 - 72)
Reporting group description: Subjects assigned to the guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders were re-randomized to either guselkumab or placebo. Subjects re-randomized to guselkumab, received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32 and then q8w through Week 72. Subjects re-randomized to placebo, received placebo matched to guselkumab SC injection q4w through Week 72 or until loss of \geq 50% in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab.	
Reporting group title	Adalimumab then Guselkumab 100 mg (Week 28 - 72)
Reporting group description: Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90	

response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 36 and 44. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of $\geq 50\%$ in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were treated with guselkumab.

Reporting group title	Adalimumab (After ACP)
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Reporting group description:

Subjects who received adalimumab 80 mg at Week 0 and adalimumab 40 mg at Week 1 and every other week through Week 23 were assessed for PASI 90 response at Week 28. PASI 90 responders who did not crossover to guselkumab upon loss of $\geq 50\%$ in the improvement in PASI and did not continue any treatment at Week 28 are reported in this arm.

Reporting group title	Guselkumab Combined
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Reporting group description:

All subjects who received guselkumab 100 mg subcutaneously q8w at Week 76 and thereafter through Week 252.

Reporting group title	Adalimumab then Guselkumab 100 mg (Week 72 - 264)
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Reporting group description:

All subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

Subject analysis set title	Guselkumab Combined
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

All subjects who crossed over to receive guselkumab 100 mg subcutaneously at Week 16 from placebo group and subjects who were randomized to guselkumab 100 mg group at Week 0. Placebo crossover subjects were included in the guselkumab column after crossover to guselkumab.

Subject analysis set title	Withdrawal Group (Through Week 72)
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Subjects in withdrawal group received guselkumab 100 mg SC injection at Weeks 0, 4 and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, 5 and q2w through Week 15 to maintain the blind during PCP. Subjects received placebo matched to guselkumab SC injection at Week 16 then guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at q2w from Week 17 through Week 23. These subjects who were PASI 90 responders at Week 28 were randomized to receive placebo matched to guselkumab SC injection at Week 28 and q4w thereafter through Week 72 until loss of $\geq 50\%$ in the improvement in PASI.

Subject analysis set title	Guselkumab Maintenance Group (Through Week 72)
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Subjects of maintenance group received guselkumab 100 mg SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 then placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, 5, 7, and q2w through Week 15. Subjects received placebo matched to guselkumab SC injection at Week 16 then guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at q2w from Week 17 through Week 23. These subjects were PASI 90 responders who were randomized to receive guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32, 40 and thereafter through Week 72.

Subject analysis set title	Guselkumab 100 mg
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Subjects received guselkumab 100 mg SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 then placebo matched to adalimumab (1 SC injection) at Weeks 1, 3, 5 and q2w thereafter through Week 15. Subjects received placebo matched to guselkumab SC injection at Week 16 then guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.

Subject analysis set title	Adalimumab
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Subject analysis set type	Intention-to-treat
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Subject analysis set description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Weeks 1, 3, 5 and every other week thereafter through Week 15 and placebo matched to

guselkumab SC injection at Weeks 0, 4, and 12. Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) q2w from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.

Subject analysis set title	Adalimumab then Guselkumab 100 mg (Week 28 - 264)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 36 and 44. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of $\geq 50\%$ in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were treated with guselkumab. All subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

Primary: Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Placebo Group at Week 16

End point title	Percentage of Subjects Who Achieved an Investigator's Global Assessment (IGA) Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Placebo Group at Week 16 ^[1]
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End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Primary
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End point timeframe:

Week 16

Notes:

[1] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo (Week 0 - 16)	Guselkumab 100 mg (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248	495		
Units: percentage of subjects				
number (not applicable)	8.5	84.1		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16)
Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Primary: Percentage of Subjects Who Achieved Psoriasis Area and Severity Index (PASI) 90 Response in the Guselkumab Group Compared to the Placebo Group at Week 16

End point title	Percentage of Subjects Who Achieved Psoriasis Area and Severity Index (PASI) 90 Response in the Guselkumab Group Compared to the Placebo Group at Week 16 ^[2]
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these area was assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Primary
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End point timeframe:

Week 16

Notes:

[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: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo (Week 0 - 16)	Guselkumab 100 mg (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248	496		
Units: percentage of subjects				
number (not applicable)	2.4	70.0		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16)
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) in the Guselkumab Group Compared to the Adalimumab Group at Week 24

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) in the Guselkumab Group Compared to the Adalimumab Group at Week 24
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End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or who did not come for evaluation at Week 24 were considered nonresponders) was used to impute missing values.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Guselkumab 100 mg	Adalimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	496	248		
Units: percentage of subjects				
number (not applicable)	51.8	31.5		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Guselkumab 100 mg v Adalimumab
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 24

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 24
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End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or who did not come for evaluation at Week 24 were considered nonresponders) was used to impute missing values.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Guselkumab 100 mg	Adalimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	496	248		
Units: percentage of subjects				
number (not applicable)	83.5	64.9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Guselkumab 100 mg v Adalimumab
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 24

End point title	Percentage of Subjects Who Achieved PASI 90 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 24
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set. Nonresponder imputation (subjects who met treatment-failure criteria before Week 24 or who did not come for evaluation at Week 24 were considered nonresponders) was used to impute missing values.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Guselkumab 100 mg	Adalimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	496	248		
Units: percentage of subjects				
number (not applicable)	75.2	54.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Guselkumab 100 mg v Adalimumab
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Cumulative Maintenance Rate of PASI 90 Response in the Placebo Group Compared to the Guselkumab Group Through Week 48 to Evaluate Loss of a PASI 90 Response

End point title	Cumulative Maintenance Rate of PASI 90 Response in the Placebo Group Compared to the Guselkumab Group Through Week 48 to Evaluate Loss of a PASI 90 Response
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Cumulative maintenance rate was defined as percentage of subjects who maintained their PASI 90 response through Week 48. Randomized analysis set who achieved a PASI 90 response at Week 28, were re-randomized to continue guselkumab or receive placebo and with at least one PASI assessment post Week 28.

End point type	Secondary
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End point timeframe:

Through Week 48

End point values	Withdrawal Group (Through Week 72)	Guselkumab Maintenance Group (Through Week 72)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	181	193		
Units: percentage of subjects				
number (not applicable)	35.4	81.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

p value is based on the log-rank test stratified by investigator site (pooled).

Comparison groups	Withdrawal Group (Through Week 72) v Guselkumab Maintenance Group (Through Week 72)
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Number of subjects included in analysis	374
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Logrank

Secondary: Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16 in the Guselkumab Group Compared to the Placebo Group

End point title	Change From Baseline in Dermatology Life Quality Index (DLQI) Score at Week 16 in the Guselkumab Group Compared to the Placebo Group ^[3]
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End point description:

The DLQI is a 10-item questionnaire that measures the impact of skin disease on participant's quality of life (QoL). Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much); where higher scores indicate more impact on QoL. The DLQI total score ranges from 0 (not at all) to 30 (very much): 0-1 = no effect at all on the subject's life; 2-6 = small effect on the subject's life; 7-12 = moderate effect on the subject's life; 13-18 = very large effect on the subject's life; 19-30 = extremely large effect on the subject's life. Higher scores indicate more impact on QoL of subjects. Randomized analysis set included all subjects who were randomized at Week 0 and with a baseline DLQI score.

End point type	Secondary
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End point timeframe:

Baseline, Week 16

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: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo (Week 0 - 16)	Guselkumab 100 mg (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	248	495		
Units: units on a scale				
arithmetic mean (standard deviation)	-2.6 (± 6.85)	-11.23 (± 6.82)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

p value is based on analysis of variance (ANOVA) model stratified by investigator site (pooled).

Comparison groups	Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16)
Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 16

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) in the Guselkumab Group Compared to the Adalimumab Group at Week 16 ^[4]
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End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Secondary
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End point timeframe:

Week 16

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: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg (Week 0 - 16)	Adalimumab (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	496	248		
Units: percentage of subjects				
number (not applicable)	84.1	67.7		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

p value is based on 1-sided Mantel Haenszel (MH) Z-test adjusted for investigator site (pooled).

Comparison groups	Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16)
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[5]
P-value	< 0.001
Method	MH Z-test
Parameter estimate	Difference in Percentage
Point estimate	16.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	10
upper limit	23.2

Notes:

[5] - non-inferiority margin= -10.0%

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).

Comparison groups	Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16)
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Percentage of Subjects Who Achieved PASI 90 Response, in the Guselkumab Group Compared to the Adalimumab Group at Week 16

End point title	Percentage of Subjects Who Achieved PASI 90 Response, in the Guselkumab Group Compared to the Adalimumab Group at Week 16 ^[6]
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Randomized analysis set included all subjects who were randomized at Week 0. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Secondary
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End point timeframe:

Week 16

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: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg (Week 0 - 16)	Adalimumab (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	495	248		
Units: percentage of subjects				
number (not applicable)	70.0	46.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
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Statistical analysis description:

p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).

Comparison groups	Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16)
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Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: p value is based on 1-sided MH Z-test adjusted for investigator site (pooled).	
Comparison groups	Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16)
Number of subjects included in analysis	743
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[7]
P-value	< 0.001
Method	MH Z-test
Parameter estimate	Difference in Percentage
Point estimate	23.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	16
upper limit	30.4

Notes:

[7] - non-inferiority margin= -10.0%

Secondary: Percentage of Subjects Who Achieved PASI 75 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16

End point title	Percentage of Subjects Who Achieved PASI 75 Response in the Guselkumab Group Compared to the Adalimumab Group at Week 16 ^[8]
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End point description:

The PASI is a system used for assessing and grading the severity of psoriatic lesions. In the PASI system, the body is divided into 4 regions: the head, trunk, upper extremities, and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. The PASI produces a numeric score that can range from 0 to 72. A higher score indicates more severe disease. A PASI 75 response represents subjects who achieved at least a 75 percent improvement from baseline in the PASI score. Randomized analysis set. Nonresponder imputation (subjects who met treatment-failure criteria before Week 16 or who did not come for evaluation at week 16 were considered nonresponders) was used to impute missing values.

End point type	Secondary
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End point timeframe:

Week 16

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: Endpoint was planned to be analyzed for specified arms only.

End point values	Guselkumab 100 mg (Week 0 - 16)	Adalimumab (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	496	248		
Units: percentage of subjects				
number (not applicable)	86.3	68.5		

Statistical analyses

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).	
Comparison groups	Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16)
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: p value is based on 1-sided MH Z-test adjusted for investigator site (pooled).	
Comparison groups	Guselkumab 100 mg (Week 0 - 16) v Adalimumab (Week 0 - 16)
Number of subjects included in analysis	744
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[9]
P-value	< 0.001
Method	MH Z-test
Parameter estimate	Difference in percentage
Point estimate	17.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.4
upper limit	24.4

Notes:

[9] - non-inferiority margin= -10%

Secondary: Percentage of Subjects who Achieved a Scalp-specific Investigator's Global Assessment (ss-IGA) Score of 0 or 1 and at Least a 2-Grade Improvement From Baseline at Week 16 in the Guselkumab Group Compared to the Placebo Group

End point title	Percentage of Subjects who Achieved a Scalp-specific Investigator's Global Assessment (ss-IGA) Score of 0 or 1 and at Least a 2-Grade Improvement From Baseline at Week 16 in the Guselkumab Group Compared to the Placebo Group ^[10]
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End point description:

The ss-IGA instrument is used to evaluate the disease severity of scalp psoriasis. The lesions were assessed in terms of the clinical signs of redness, thickness, and scaliness, which are scored on a 5-point scale ranging from 0 = absence of disease, 1 = very mild disease, 2 = mild disease, 3 = moderate disease, and 4 = severe disease. Population analyzed included only randomized subjects who had an ss-IGA score greater than or equal to (\geq) 2 at baseline. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint.

End point type	Secondary
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End point timeframe:

Week 16

Notes:

[10] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo (Week 0 - 16)	Guselkumab 100 mg (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	202	408		
Units: percentage of subjects				
number (not applicable)	10.9	80.6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
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Statistical analysis description:

p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).

Comparison groups	Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16)
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Number of subjects included in analysis	610
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Analysis specification	Pre-specified
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Analysis type	superiority
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P-value	< 0.001
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Method	Cochran-Mantel-Haenszel chi-square test
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Secondary: Change From Baseline in Psoriasis Symptom and Sign Diary (PSSD) Symptom Score at Week 16 in the Guselkumab Group Compared to the Placebo Group

End point title	Change From Baseline in Psoriasis Symptom and Sign Diary (PSSD) Symptom Score at Week 16 in the Guselkumab Group Compared to the Placebo Group ^[11]
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End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Symptom [or Sign] score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. PSSD analysis set included all subjects who had baseline PSSD scores as the average score of at least 4 days out of the 7 days prior to the Week 0 visit. This endpoint was planned to be compared only for groups Placebo and Guselkumab 100 mg.

End point type	Secondary
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End point timeframe:

Baseline and Week 16

Notes:

[11] - 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: Endpoint was planned to be analyzed for specified arms only.

End point values	Placebo (Week 0 - 16)	Guselkumab 100 mg (Week 0 - 16)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	198	411		
Units: units on a scale				
arithmetic mean (standard deviation)	-8.3 (± 23.67)	-40.4 (± 26.52)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
p value is based on ANOVA model stratified by investigator site (pooled).	
Comparison groups	Placebo (Week 0 - 16) v Guselkumab 100 mg (Week 0 - 16)
Number of subjects included in analysis	609
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	ANOVA

Secondary: Percentage of Subjects who Achieved a PSSD Symptom Score of 0 in the Guselkumab Group Compared to the Adalimumab Group at Week 24

End point title	Percentage of Subjects who Achieved a PSSD Symptom Score of 0 in the Guselkumab Group Compared to the Adalimumab Group at Week 24
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End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Symptom [or Sign] score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. PSSD analysis set included all subjects who were randomized at Week 0 and had baseline PSSD score greater than 0. This endpoint was planned to be compared only for groups Placebo and Guselkumab 100 mg.

End point type	Secondary
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End point timeframe:

Week 24

End point values	Guselkumab 100 mg	Adalimumab		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	410	200		
Units: percentage of subjects				
number (not applicable)	35.1	22.5		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: p value is based on the Cochran-Mantel-Haenszel chi-square test stratified by investigator site (pooled).	
Comparison groups	Guselkumab 100 mg v Adalimumab
Number of subjects included in analysis	610
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel chi-square test

Secondary: Cumulative Maintenance Rate of PASI 90 Response in the Guselkumab Withdrawal Group Compared to the Guselkumab Maintenance Group Through Week 72 to Evaluate Loss of a PASI 90 Response

End point title	Cumulative Maintenance Rate of PASI 90 Response in the Guselkumab Withdrawal Group Compared to the Guselkumab Maintenance Group Through Week 72 to Evaluate Loss of a PASI 90 Response
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End point description:

In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6 and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score ranging from 0 to 72. Higher score=more severe disease. PASI 90 response represents subjects who achieved at least a 90 percent improvement from baseline in PASI score. Cumulative maintenance rate was determined for subjects who were withdrawn from study medication and who maintained guselkumab every 8 weeks dosing schedule and was defined as percentage of subjects who maintained their PASI 90 response through Week 72. Population analyzed included PASI 90 responders at Week 28 and who were randomized at Week 28 and treated with guselkumab. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint.

End point type	Secondary
End point timeframe: Through Week 72	

End point values	Withdrawal Group (Through Week 72)	Guselkumab Maintenance Group (Through Week 72)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	181	193		
Units: percentage of subjects				
number (not applicable)	11.5	86		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 90 Response at Week 252

End point title	Percentage of Subjects Who Achieved PASI 90 Response at Week 252
End point description:	
<p>In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 to 72. Higher score= more severe disease. PASI 90 response signify subjects who achieved at least a 90 percent improvement from baseline in the PASI score. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.</p>	
End point type	Secondary
End point timeframe:	
Week 252	

End point values	Guselkumab Combined	Adalimumab then Guselkumab 100 mg (Week 28 - 264)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	560	177		
Units: percentage of subjects				
number (not applicable)	82.0	79.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved PASI 75 Response at Week 252

End point title	Percentage of Subjects Who Achieved PASI 75 Response at Week 252
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End point description:

In PASI system, body is divided into 4 regions: head, trunk, upper and lower extremities. Each of these areas were assessed separately for the percentage of the area involved, which translates to a numeric score ranging from 0 to 6, and for erythema, induration, and scaling, which are each rated on a scale of 0 to 4. PASI produces a numeric score that can range from 0 to 72. Higher score= more severe disease. PASI 75 response signify subjects who achieved at least a 75 percent improvement from baseline in the PASI score. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary
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End point timeframe:

Week 252

End point values	Guselkumab Combined	Adalimumab then Guselkumab 100 mg (Week 28 - 264)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	560	177		
Units: percentage of subjects				
number (not applicable)	93.4	92.7		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) at Week 252

End point title	Percentage of Subjects Who Achieved an IGA Score of Cleared (0) or Minimal (1) at Week 252
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End point description:

The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions are graded for induration, erythema, and scaling. The subject's psoriasis was assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary
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End point timeframe:

Week 252

End point values	Guselkumab Combined	Adalimumab then Guselkumab 100 mg (Week 28 - 264)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	559	177		
Units: percentage of subjects				
number (not applicable)	85.0	83.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects with a DLQI Score of 0 or 1 at Week 252

End point title	Percentage of Subjects with a DLQI Score of 0 or 1 at Week 252
End point description:	
DLQI measures impact of skin disease on subject's QoL. Each question was evaluated on a 4-point scale ranging from 0 (not at all) to 3 (very much). DLQI total score ranges from 0 (not at all) to 30 (very much): 0-1=no effect on subject's life; 2-6=small effect; 7-12=moderate effect; 13-18=very large effect; 19-30=extremely large effect. DLQI was calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. Higher scores indicate more impact on subject's QoL. Population analyzed included subjects randomized at Week 0 and treated with guselkumab with baseline DLQI score >1. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.	
End point type	Secondary
End point timeframe:	
Week 252	

End point values	Guselkumab Combined	Adalimumab then Guselkumab 100 mg (Week 28 - 264)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	550	173		
Units: percentage of subjects				
number (not applicable)	71.1	69.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a PSSD Symptom Score of 0 at Week 252

End point title	Percentage of Subjects who Achieved a PSSD Symptom Score
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End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Symptom score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab with baseline PSSD symptom score >0. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary
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End point timeframe:

Week 252

End point values	Guselkumab Combined	Adalimumab then Guselkumab 100 mg (Week 28 - 264)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	460	145		
Units: percentage of subjects				
number (not applicable)	42.0	36.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a PSSD Sign Score of 0 at Week 252

End point title	Percentage of Subjects who Achieved a PSSD Sign Score of 0 at Week 252
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End point description:

The PSSD consisted of 11 items covering symptoms (itch, pain, stinging, burning, and skin tightness) and patient-observable signs (skin dryness, cracking, scaling, shedding or flaking, redness, and bleeding) using 0 (absent) to 10 (worst imaginable) numerical rating scales for severity. The average value is converted into 0-100 scoring, such that Sign score=average value*10, where, 0=least severe and 100=most severe and higher score indicates more severe disease. Population analyzed included subjects who were randomized at Week 0 and treated with guselkumab with baseline PSSD sign score >0. The analysis was performed using observed data after applying treatment failure rules. Here, N (Number of subjects analyzed) signifies subjects who were analyzed for this endpoint. As per planned analysis, subjects from the baseline guselkumab group and the placebo crossover group were combined into a single guselkumab group for assessment of this endpoint.

End point type	Secondary
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End point timeframe:

Week 252

End point values	Guselkumab Combined	Adalimumab then Guselkumab 100 mg (Week 28 - 264)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	461	145		
Units: percentage of subjects				
number (not applicable)	31.0	24.1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline (Week 0) up to Week 264

Adverse event reporting additional description:

All subjects who were randomized at Week 0, received ≥ 1 dose of study agent (partial or complete). Subjects who discontinued treatment prematurely were followed for at least 12 weeks after last dose and who discontinued in the previous period and had safety follow-up continuing in the current period, were counted in both the periods.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Guselkumab 100 mg (Week 0 - 16)
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Reporting group description:

Subjects received guselkumab 100 milligram (mg) SC injection at Weeks 0, 4 and 12, and placebo matched to adalimumab (2 SC injections) at Week 0 followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 during PCP.

Reporting group title	Placebo (Week 0 - 16)
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Reporting group description:

Subjects received placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 and placebo matched to adalimumab (2 SC injections) at Week 0, followed by placebo matched to adalimumab (1 SC injection) at Week 1 and every other week thereafter through Week 15 to maintain the blind during placebo controlled period (PCP).

Reporting group title	Placebo then Guselkumab 100 mg (Week 16 - 28)
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Reporting group description:

Subjects who started receiving placebo in the first period were crossed over to receive guselkumab 100 mg SC injection at Weeks 16 and 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21, and 23 during the active comparator controlled period (ACP).

Reporting group title	Adalimumab (Week 0 - 16)
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Reporting group description:

Subjects received adalimumab 80 mg (2 SC injections) at Week 0 followed by adalimumab 40 mg (1 SC injection) at Week 1 and every other week thereafter through Week 15 and placebo matched to guselkumab SC injection at Weeks 0, 4, and 12 during PCP.

Reporting group title	Guselkumab 100 mg (Week 16 - 28)
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Reporting group description:

Subjects who started receiving guselkumab in the first period, received placebo matched to guselkumab SC injection at Week 16 followed by guselkumab 100 mg SC injection at Week 20 and placebo matched to adalimumab (1 SC injection) at Weeks 17, 19, 21 and 23.

Reporting group title	Adalimumab (Week 16 - 28)
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Reporting group description:

Subjects who received adalimumab in the first period, continued to receive adalimumab 40 mg (1 SC injection) every 2 weeks (q2w) from Week 17 through Week 23 and placebo matched to guselkumab SC injection at Weeks 16 and 20.

Reporting group title	Placebo then Guselkumab 100 mg (Week 28 - 264)
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Reporting group description:

Subjects assigned to the placebo, then guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and then every 8 weeks (q8w) thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders at Week 28 received placebo matched to guselkumab SC injection at Week 28 and every 4 weeks (q4w) thereafter through Week 72 or until loss of greater than or equal to (\geq) 50 percentage (%) in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab. Thereafter, subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.

Reporting group title	Guselkumab 100 mg (Week 28 - 264)
Reporting group description:	
Subjects assigned to the guselkumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders at Week 28 received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab at Week 32 and then q8w through Week 72. Subjects who were PASI 90 responders were re-randomized to either guselkumab or placebo. Subjects re-randomized to guselkumab, received guselkumab 100 mg SC injection at Week 28 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Weeks 32 and then q8w through Week 72. Subjects re-randomized to placebo, received placebo matched to guselkumab SC injection q4w through Week 72 or until loss of $\geq 50\%$ in the improvement in PASI (Withdrawal and retreatment period). If they lost response according to this definition, they were retreated with guselkumab. Thereafter, subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252.	
Reporting group title	Adalimumab Then Guselkumab 100 mg (Week 28 - 264)
Reporting group description:	
Subjects who were assigned to the adalimumab arm through Week 28 were assessed for PASI 90 response at Week 28. Subjects who were PASI 90 non-responders received guselkumab 100 mg SC injection at Week 28 and 32 and q8w thereafter through Week 72 and placebo matched to guselkumab SC injection at Week 36 and q8w through Week 72. Subjects who were PASI 90 responders, received placebo matched to guselkumab SC injection q4w thereafter through Week 72 or until loss of $\geq 50\%$ in the improvement in PASI. If they lost response according to this definition, they were treated with guselkumab. Thereafter, subjects received guselkumab 100 mg at Week 76 and then q8w through Week 252. The presentation of data from the adalimumab group from Week 28 to Week 264 is divided into 2 arms (adalimumab then guselkumab 100 mg (Week 28 - 264) and adalimumab (After ACP) in order to represent exposure to 2 different active study agents (adalimumab vs guselkumab).	
Reporting group title	Adalimumab (After ACP)
Reporting group description:	
Subjects who received adalimumab 80 mg at Week 0 and adalimumab 40 mg at Week 1 and every other week through Week 23 were assessed for PASI 90 response at Week 28. PASI 90 responders who did not crossover to guselkumab upon loss of $\geq 50\%$ in the improvement in PASI and did not continue any treatment at Week 28 are reported in this arm.	

Serious adverse events	Guselkumab 100 mg (Week 0 - 16)	Placebo (Week 0 - 16)	Placebo then Guselkumab 100 mg (Week 16 - 28)
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 494 (1.62%)	3 / 248 (1.21%)	5 / 233 (2.15%)
number of deaths (all causes)	0	1	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-Cell Lymphoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial Carcinoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Cancer			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ependymoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Pseudotumour			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondroma			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Carcinoma Stage Iv			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinonasal Papilloma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Haematoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic Pregnancy			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Hypersensitivity			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Miscarriage of Partner			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Nasal Septum Deviation			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Fibrosis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Polyp			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Device Dislocation			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Alanine Aminotransferase Increased subjects affected / exposed	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Chest Injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral Injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ligament Rupture			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve Injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Injury Cervical			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulnar Nerve Injury			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Unstable			
subjects affected / exposed	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial Infarction			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Cerebellar Stroke			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Coma			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis Transverse			
subjects affected / exposed	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Nerve Lesion			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Nerve Paresis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Retinal Vein Occlusion			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Duodenal Perforation			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	1 / 248 (0.40%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Submaxillary Gland Enlargement			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Chronic			
subjects affected / exposed	0 / 494 (0.00%)	1 / 248 (0.40%)	0 / 233 (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
Cholelithiasis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Steatosis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Nephrolithiasis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular Weakness			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Chest Pain			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 494 (0.00%)	1 / 248 (0.40%)	0 / 233 (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
Osteoarthritis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic Arthropathy			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Perforated			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 Tonsillitis			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated Tuberculosis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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	1 / 494 (0.20%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiv Infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection Site Abscess			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar Abscess			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Cyst			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal Abscess			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft Tissue Infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular Neuronitis			

subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	1 / 233 (0.43%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	0 / 494 (0.00%)	0 / 248 (0.00%)	0 / 233 (0.00%)
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	Adalimumab (Week 0 - 16)	Guselkumab 100 mg (Week 16 - 28)	Adalimumab (Week 16 - 28)
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 248 (2.42%)	10 / 481 (2.08%)	3 / 240 (1.25%)
number of deaths (all causes)	3	0	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-Cell Lymphoma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial Carcinoma			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endometrial Cancer			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ependymoma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Pseudotumour			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondroma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic Carcinoma Stage Iv			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (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
Rectal Cancer			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinonasal Papilloma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Haematoma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic Pregnancy			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden Death			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Hypersensitivity			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Miscarriage of Partner			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (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
Prostatitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Haemorrhage			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Nasal Septum Deviation			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Fibrosis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus Polyp			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Device Dislocation			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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	1 / 248 (0.40%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Chest Injury			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral Injury			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Injury			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Sprain			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus Injury			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve Injury			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Injury Cervical			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haemorrhage			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulnar Nerve Injury			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	1 / 248 (0.40%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Unstable			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (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
Coronary Artery Disease			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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	1 / 248 (0.40%)	1 / 481 (0.21%)	0 / 240 (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
Myocardial Ischaemia			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Cerebellar Stroke			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Coma			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis Transverse			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Nerve Lesion			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Nerve Paresis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			

subjects affected / exposed	0 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal Vein Occlusion			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Duodenal Perforation			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 248 (0.40%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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	1 / 248 (0.40%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Irritable Bowel Syndrome			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss Syndrome			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (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
Pancreatitis Acute			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Submaxillary Gland Enlargement			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Chronic			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Steatosis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			

Arthralgia			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Chest Pain			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic Arthropathy			
subjects affected / exposed	1 / 248 (0.40%)	0 / 481 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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			
Appendicitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Perforated			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 Tonsillitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated Tuberculosis			
subjects affected / exposed	1 / 248 (0.40%)	0 / 481 (0.00%)	0 / 240 (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
Diverticulitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hiv Infection			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection Site Abscess			
subjects affected / exposed	1 / 248 (0.40%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar Abscess			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal Cyst			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal Abscess			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft Tissue Infection			
subjects affected / exposed	0 / 248 (0.00%)	1 / 481 (0.21%)	0 / 240 (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
Tuberculosis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	1 / 240 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular Neuronitis			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			

subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	0 / 248 (0.00%)	0 / 481 (0.00%)	0 / 240 (0.00%)
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	Placebo then Guselkumab 100 mg (Week 28 - 264)	Guselkumab 100 mg (Week 28 - 264)	Adalimumab Then Guselkumab 100 mg (Week 28 - 264)
Total subjects affected by serious adverse events			
subjects affected / exposed	36 / 229 (15.72%)	66 / 473 (13.95%)	36 / 220 (16.36%)
number of deaths (all causes)	1	0	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-Cell Lymphoma			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (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
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
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	2 / 229 (0.87%)	0 / 473 (0.00%)	0 / 220 (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
Bronchial Carcinoma			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Endometrial Cancer			

subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Ependymoma			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory Pseudotumour			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Lipoma			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondroma			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Pancreatic Carcinoma Stage Iv			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Prostate Cancer			

subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal Cancer			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinonasal Papilloma			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	2 / 229 (0.87%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicose Vein			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
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, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ectopic Pregnancy			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Sudden Death			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
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 Hypersensitivity			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Miscarriage of Partner			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostatitis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Haemorrhage			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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			
Nasal Septum Deviation			
subjects affected / exposed	0 / 229 (0.00%)	2 / 473 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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 Fibrosis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Failure			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Sinus Polyp			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Sleep Apnoea Syndrome			

subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Device Dislocation			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcoholism			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Anxiety			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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			
Chest Injury			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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

Concussion			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral Injury			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye Injury			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Head Injury			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint Dislocation			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament Rupture			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Ligament Sprain			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower Limb Fracture			

subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Meniscus Injury			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Fractures			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple Injuries			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nerve Injury			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Radius Fracture			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Cord Injury Cervical			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Subdural Haematoma			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haemorrhage			

subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ulnar Nerve Injury			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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			
Acute Myocardial Infarction			
subjects affected / exposed	2 / 229 (0.87%)	4 / 473 (0.85%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 2	1 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina Pectoris			
subjects affected / exposed	1 / 229 (0.44%)	1 / 473 (0.21%)	0 / 220 (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
Angina Unstable			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial Fibrillation			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
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 Failure			

subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Myocardial Infarction			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	2 / 220 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Myocardial Ischaemia			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebellar Stroke			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Diabetic Coma			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (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
Epilepsy			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelitis Transverse			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelopathy			

subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Peripheral Nerve Lesion			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Peripheral Nerve Paresis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 229 (0.44%)	1 / 473 (0.21%)	0 / 220 (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
Thrombocytopenia			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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			

Retinal Vein Occlusion			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Duodenal Perforation			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoidal Haemorrhage			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Haemorrhoids			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
subjects affected / exposed	1 / 229 (0.44%)	2 / 473 (0.42%)	0 / 220 (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
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Mallory-Weiss Syndrome			

subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Submaxillary Gland Enlargement			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical Hernia			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (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
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
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	0 / 229 (0.00%)	0 / 473 (0.00%)	2 / 220 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis Chronic			

subjects affected / exposed	0 / 229 (0.00%)	2 / 473 (0.42%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	2 / 220 (0.91%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic Steatosis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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			
Nephrolithiasis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal Colic			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
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 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Muscular Weakness			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal Pain			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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 / 229 (0.44%)	2 / 473 (0.42%)	3 / 220 (1.36%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic Arthropathy			
subjects affected / exposed	1 / 229 (0.44%)	3 / 473 (0.63%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Synovitis			

subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	2 / 229 (0.87%)	4 / 473 (0.85%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis Perforated			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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 / 229 (0.00%)	4 / 473 (0.85%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic Sinusitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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 Tonsillitis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Cystitis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Disseminated Tuberculosis			

subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Hiv Infection			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Injection Site Abscess			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar Abscess			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Pilonidal Cyst			
subjects affected / exposed	1 / 229 (0.44%)	0 / 473 (0.00%)	0 / 220 (0.00%)
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	2 / 229 (0.87%)	2 / 473 (0.42%)	2 / 220 (0.91%)
occurrences causally related to treatment / all	1 / 2	1 / 2	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retroperitoneal Abscess			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	1 / 220 (0.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft Tissue Infection			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tuberculosis			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Urosepsis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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
Vestibular Neuronitis			
subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound Infection			
subjects affected / exposed	0 / 229 (0.00%)	0 / 473 (0.00%)	0 / 220 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			

subjects affected / exposed	0 / 229 (0.00%)	1 / 473 (0.21%)	0 / 220 (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	Adalimumab (After ACP)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 11 (9.09%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-Cell Lymphoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign Neoplasm of Thyroid Gland			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast Cancer			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchial Carcinoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endometrial Cancer			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ependymoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Fibroadenoma of Breast				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inflammatory Pseudotumour				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lipoma				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malignant Melanoma				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteochondroma				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatic Carcinoma Stage Iv				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Prostate Cancer				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rectal Cancer				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sinonasal Papilloma				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine Leiomyoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicose Vein			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ectopic Pregnancy			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Non-Cardiac Chest Pain			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden Death			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic Reaction			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug Hypersensitivity			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Miscarriage of Partner			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian Cyst			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostatitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Uterine Haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Nasal Septum Deviation			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary Embolism			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary Fibrosis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory Failure			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinus Polyp			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sleep Apnoea Syndrome			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Device Dislocation			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Alcoholism			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anxiety			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide Attempt			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Chest Injury			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniocerebral Injury			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Eye Injury				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur Fracture				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head Injury				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Joint Dislocation				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament Rupture				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament Sprain				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower Limb Fracture				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meniscus Injury				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple Fractures				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple Injuries				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nerve Injury				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius Fracture				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Cord Injury Cervical				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural Haematoma				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural Haemorrhage				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ulnar Nerve Injury				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina Pectoris			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina Unstable			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial Fibrillation			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bradycardia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac Failure			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coronary Artery Disease			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial Infarction			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial Ischaemia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebellar Stroke			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic Coma			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelitis Transverse			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelopathy			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral Nerve Lesion			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral Nerve Paresis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Retinal Vein Occlusion			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Duodenal Perforation			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastritis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Haemorrhage				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoidal Haemorrhage				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhoids				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal Hernia				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Irritable Bowel Syndrome				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mallory-Weiss Syndrome				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis Acute				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Submaxillary Gland Enlargement			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical Hernia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis Acute			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis Chronic			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatic Steatosis			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Colic			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ureterolithiasis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary Retention			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral Disc Protrusion			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscular Weakness			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal Pain			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psoriatic Arthropathy			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Synovitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Appendicitis Perforated			

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchitis				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic Sinusitis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic Tonsillitis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated Tuberculosis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hiv Infection				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injection Site Abscess				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonsillar Abscess				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pilonidal Cyst				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Retroperitoneal Abscess				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Soft Tissue Infection				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tuberculosis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urosepsis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vestibular Neuronitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wound Infection			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Guselkumab 100 mg (Week 0 - 16)	Placebo (Week 0 - 16)	Placebo then Guselkumab 100 mg (Week 16 - 28)
Total subjects affected by non-serious adverse events subjects affected / exposed	125 / 494 (25.30%)	60 / 248 (24.19%)	33 / 233 (14.16%)
Vascular disorders Hypertension subjects affected / exposed occurrences (all)	10 / 494 (2.02%) 11	4 / 248 (1.61%) 4	1 / 233 (0.43%) 1
Cardiac disorders Cardiac Failure Congestive subjects affected / exposed occurrences (all)	0 / 494 (0.00%) 0	0 / 248 (0.00%) 0	0 / 233 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	25 / 494 (5.06%) 27	7 / 248 (2.82%) 7	5 / 233 (2.15%) 5
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Gastrooesophageal Reflux Disease subjects affected / exposed occurrences (all)	11 / 494 (2.23%) 12 1 / 494 (0.20%) 1	2 / 248 (0.81%) 2 0 / 248 (0.00%) 0	0 / 233 (0.00%) 0 0 / 233 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	8 / 494 (1.62%) 8	4 / 248 (1.61%) 4	1 / 233 (0.43%) 1
Skin and subcutaneous tissue disorders Dermatitis Contact subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	4 / 494 (0.81%) 4 1 / 494 (0.20%) 1	2 / 248 (0.81%) 2 3 / 248 (1.21%) 3	0 / 233 (0.00%) 0 0 / 233 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia			

subjects affected / exposed occurrences (all)	11 / 494 (2.23%) 12	6 / 248 (2.42%) 6	0 / 233 (0.00%) 0
Back Pain subjects affected / exposed occurrences (all)	4 / 494 (0.81%) 4	6 / 248 (2.42%) 6	0 / 233 (0.00%) 0
Infections and infestations			
Bronchitis subjects affected / exposed occurrences (all)	3 / 494 (0.61%) 3	3 / 248 (1.21%) 3	6 / 233 (2.58%) 7
Gastroenteritis subjects affected / exposed occurrences (all)	4 / 494 (0.81%) 4	1 / 248 (0.40%) 1	0 / 233 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	35 / 494 (7.09%) 36	16 / 248 (6.45%) 17	12 / 233 (5.15%) 12
Pharyngitis subjects affected / exposed occurrences (all)	7 / 494 (1.42%) 7	2 / 248 (0.81%) 2	2 / 233 (0.86%) 2
Sinusitis subjects affected / exposed occurrences (all)	3 / 494 (0.61%) 3	3 / 248 (1.21%) 3	1 / 233 (0.43%) 1
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	16 / 494 (3.24%) 17	10 / 248 (4.03%) 11	5 / 233 (2.15%) 5
Viral Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	6 / 494 (1.21%) 7	1 / 248 (0.40%) 1	1 / 233 (0.43%) 1
Metabolism and nutrition disorders			
Hyperglycaemia subjects affected / exposed occurrences (all)	2 / 494 (0.40%) 2	1 / 248 (0.40%) 1	0 / 233 (0.00%) 0

Non-serious adverse events	Adalimumab (Week 0 - 16)	Guselkumab 100 mg (Week 16 - 28)	Adalimumab (Week 16 - 28)
Total subjects affected by non-serious adverse events subjects affected / exposed	51 / 248 (20.56%)	63 / 481 (13.10%)	45 / 240 (18.75%)

Vascular disorders Hypertension subjects affected / exposed occurrences (all)	6 / 248 (2.42%) 6	4 / 481 (0.83%) 4	1 / 240 (0.42%) 1
Cardiac disorders Cardiac Failure Congestive subjects affected / exposed occurrences (all)	0 / 248 (0.00%) 0	0 / 481 (0.00%) 0	0 / 240 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	5 / 248 (2.02%) 6	6 / 481 (1.25%) 6	4 / 240 (1.67%) 4
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Gastrooesophageal Reflux Disease subjects affected / exposed occurrences (all)	4 / 248 (1.61%) 4 1 / 248 (0.40%) 1	3 / 481 (0.62%) 3 1 / 481 (0.21%) 1	3 / 240 (1.25%) 3 2 / 240 (0.83%) 2
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 248 (0.40%) 1	2 / 481 (0.42%) 2	2 / 240 (0.83%) 2
Skin and subcutaneous tissue disorders Dermatitis Contact subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	1 / 248 (0.40%) 1 5 / 248 (2.02%) 6	2 / 481 (0.42%) 2 1 / 481 (0.21%) 1	0 / 240 (0.00%) 0 1 / 240 (0.42%) 1
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back Pain subjects affected / exposed occurrences (all)	2 / 248 (0.81%) 2 0 / 248 (0.00%) 0	8 / 481 (1.66%) 8 6 / 481 (1.25%) 7	6 / 240 (2.50%) 7 0 / 240 (0.00%) 0

Infections and infestations Bronchitis subjects affected / exposed occurrences (all)	5 / 248 (2.02%) 6	3 / 481 (0.62%) 3	3 / 240 (1.25%) 3
Gastroenteritis subjects affected / exposed occurrences (all)	5 / 248 (2.02%) 5	1 / 481 (0.21%) 1	0 / 240 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	20 / 248 (8.06%) 20	18 / 481 (3.74%) 19	16 / 240 (6.67%) 17
Pharyngitis subjects affected / exposed occurrences (all)	1 / 248 (0.40%) 1	5 / 481 (1.04%) 5	2 / 240 (0.83%) 2
Sinusitis subjects affected / exposed occurrences (all)	2 / 248 (0.81%) 3	3 / 481 (0.62%) 3	2 / 240 (0.83%) 2
Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	4 / 248 (1.61%) 5	12 / 481 (2.49%) 13	6 / 240 (2.50%) 7
Viral Upper Respiratory Tract Infection subjects affected / exposed occurrences (all)	0 / 248 (0.00%) 0	0 / 481 (0.00%) 0	1 / 240 (0.42%) 1
Metabolism and nutrition disorders Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 248 (0.40%) 1	0 / 481 (0.00%) 0	2 / 240 (0.83%) 2

Non-serious adverse events	Placebo then Guselkumab 100 mg (Week 28 - 264)	Guselkumab 100 mg (Week 28 - 264)	Adalimumab Then Guselkumab 100 mg (Week 28 - 264)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	144 / 229 (62.88%)	297 / 473 (62.79%)	159 / 220 (72.27%)
Vascular disorders			
Hypertension			
subjects affected / exposed	27 / 229 (11.79%)	43 / 473 (9.09%)	20 / 220 (9.09%)
occurrences (all)	30	51	23
Cardiac disorders			

Cardiac Failure Congestive subjects affected / exposed occurrences (all)	0 / 229 (0.00%) 0	0 / 473 (0.00%) 0	0 / 220 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	9 / 229 (3.93%) 18	31 / 473 (6.55%) 44	17 / 220 (7.73%) 25
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Gastrooesophageal Reflux Disease subjects affected / exposed occurrences (all)	11 / 229 (4.80%) 13 2 / 229 (0.87%) 2	15 / 473 (3.17%) 16 12 / 473 (2.54%) 13	12 / 220 (5.45%) 14 4 / 220 (1.82%) 7
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	10 / 229 (4.37%) 12	16 / 473 (3.38%) 22	13 / 220 (5.91%) 16
Skin and subcutaneous tissue disorders Dermatitis Contact subjects affected / exposed occurrences (all) Psoriasis subjects affected / exposed occurrences (all)	2 / 229 (0.87%) 2 3 / 229 (1.31%) 3	11 / 473 (2.33%) 14 8 / 473 (1.69%) 10	6 / 220 (2.73%) 6 9 / 220 (4.09%) 9
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all) Back Pain subjects affected / exposed occurrences (all)	17 / 229 (7.42%) 36 18 / 229 (7.86%) 26	46 / 473 (9.73%) 56 25 / 473 (5.29%) 32	22 / 220 (10.00%) 32 16 / 220 (7.27%) 16
Infections and infestations Bronchitis subjects affected / exposed occurrences (all) Gastroenteritis	15 / 229 (6.55%) 16	23 / 473 (4.86%) 28	21 / 220 (9.55%) 23

subjects affected / exposed	11 / 229 (4.80%)	16 / 473 (3.38%)	11 / 220 (5.00%)
occurrences (all)	12	18	13
Nasopharyngitis			
subjects affected / exposed	67 / 229 (29.26%)	142 / 473 (30.02%)	81 / 220 (36.82%)
occurrences (all)	160	296	175
Pharyngitis			
subjects affected / exposed	18 / 229 (7.86%)	32 / 473 (6.77%)	5 / 220 (2.27%)
occurrences (all)	23	43	9
Sinusitis			
subjects affected / exposed	16 / 229 (6.99%)	23 / 473 (4.86%)	11 / 220 (5.00%)
occurrences (all)	20	32	16
Upper Respiratory Tract Infection			
subjects affected / exposed	39 / 229 (17.03%)	111 / 473 (23.47%)	49 / 220 (22.27%)
occurrences (all)	68	213	110
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	7 / 229 (3.06%)	19 / 473 (4.02%)	12 / 220 (5.45%)
occurrences (all)	13	26	15
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	4 / 229 (1.75%)	9 / 473 (1.90%)	3 / 220 (1.36%)
occurrences (all)	5	13	3

Non-serious adverse events	Adalimumab (After ACP)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 11 (36.36%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Cardiac Failure Congestive			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Nervous system disorders			
Headache			

subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Gastrooesophageal Reflux Disease			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Dermatitis Contact			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Psoriasis			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Back Pain			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 February 2015	Amendment 1 included the following major changes: assessments describing antibodies to study agent were added at Week 16 and Week 44; A physical examination and weight measurement were moved to Week 100 from Week 108, and added at Week 148; The inclusion criteria were clarified to indicate that barrier methods should be used with a spermicidal agent if spermicidal agents were available in their locale; The exclusion criterion for major surgery was clarified. The text describing serious adverse event (SAE) reporting for hospitalization was edited to address a potential contradiction with this exclusion criterion; and an exclusion criterion was added to exclude sponsor employees from participation in the study.
25 June 2015	Amendment 2 included the following change: to restrict the use of concomitant medications for psoriasis through Week 76 instead of through Week 48.
04 April 2017	Amendment 3 included the following major changes: to extend the duration of long-term extensions by 2 years thereby changing the final study visit (end of study) from Week 160 to Week 264; Updated all references to end of study and last study visit throughout the protocol; Updated to capture that, after Week 148, study drug administration information was no longer captured electronically in an eDiary, but were documented in source documents and the electronic case report form (eCRF); and minor errors were noted.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

All subjects were on guselkumab after Week 76; therefore, there was no concurrent control group within the study after Week 76.

Notes: