Clinical trial results:
A randomized, double-blind, placebo-controlled, multicenter study to demonstrate the efficacy at 16 weeks of secukinumab 150 and 300 mg s. c. and to assess safety, tolerability and long-term efficacy up to 132 weeks in subjects with moderate to severe palmoplantar psoriasis

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd. com/CtrdWeb/home.novfor complete trial results.

Summary

EudraCT number	2012-005412-25
Trial protocol	ES PT NO SK BE GB NL FI HU
Global end of trial date	02 November 2016
Results information	
Result version number	v1 (current)
This version publication date	19 July 2018
First version publication date	19 July 2018

Trial information

Trial identification	
Sponsor protocol code	CAIN457A2312
Additional study identifiers	
ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01806597
WHO universal trial number (UTN)	-

Notes:

Sponsors	
Sponsor organisation name	Novartis Pharmaceuticals
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.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	02 November 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 November 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to demonstrate the superiority of secukinumab 150 mg and/or 300 mg compared to placebo in patients with moderate to severe palmoplantar psoriasis as assessed by the palmoplantar Investigator's Global Assessment (ppIGA) at Week 16.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 June 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 22
Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Canada: 20
Country: Number of subjects enrolled	Finland: 7
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	Hungary: 19
Country: Number of subjects enrolled	Israel: 19
Country: Number of subjects enrolled	Netherlands: 15
Country: Number of subjects enrolled	Norway: 6
Country: Number of subjects enrolled	Portugal: 12
Country: Number of subjects enrolled	Russian Federation: 20
Country: Number of subjects enrolled	Slovakia: 10
Country: Number of subjects enrolled	Spain: 12
Country: Number of subjects enrolled	Turkey: 10
Country: Number of subjects enrolled	United States: 23

Worldwide total number of subjects	205
EEA total number of subjects	91

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	176
From 65 to 84 years	29
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All randomized patients were included in the FAS for efficacy analyses. 6 patients who were randomized to AIN457 150 mg group and 5 patients who were randomized to AIN457 300 mg group were excluded from the Safety
set as patients did not receive any dose of study drug during
Treatment Period 2 (on or after Week 16).

Period 1

Period 1 title	Treatment Period 1
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	AIN457 150mg

Arm description:

AIN457 150mg sub-cutaneous (s.c.) injection plus a placebo AIN457 s.c. injection once weekly for 5 weeks followed by dosing every 4 weeks

Arm type	Experimental
Investigational medicinal product name	secukinumab 150 mg
Investigational medicinal product code	AIN457
Other name	secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg

Arm title	AIN457 300 mg

Arm description:

AIN457 300 mg (2 s.c. injections of the 150 mg dose) once weekly for 5 weeks followed by dosing every 4 weeks

Arm type	Experimental
Investigational medicinal product name	secukinumab 300 mg
Investigational medicinal product code	AIN457
Other name	secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg

Arm title	Placebo

Arm description:

placebo AIN457 (2 sc injections) once weekly for 5 weeks, followed by dosing every 4 weeks.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

placebo

Number of subjects in period 1	AIN457 150mg	AIN457 300 mg	Placebo
Started	68	69	68
Completed	63	64	63
Not completed	5	5	5
Consent withdrawn by subject	3	2	2
Physician decision	-	1	-
Adverse event, non-fatal	1	1	2
Lack of efficacy	1	-	1
Protocol deviation	-	1	-

Period 2

Period 2 title	Treatment Period 2
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	AIN457 150mg

Arm description:

AIN457 150mg sub-cutaneous (s.c.) injection plus a placebo AIN457 s.c. injection once weekly for 5 weeks followed by dosing every 4 weeks

Arm type	Experimental
Investigational medicinal product name	secukinumab 150 mg
Investigational medicinal product code	AIN457
Other name	secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg

Arm title	AIN457 300 mg

Arm description:

AIN457 300 mg (2 s.c. injections of the 150 mg dose) once weekly for 5 weeks followed by dosing every 4 weeks

Arm type	Experimental
Investigational medicinal product name	secukinumab 300 mg
Investigational medicinal product code	AIN457
Other name	secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
300 mg

Arm title	Placebo - AIN457 150 mg

Arm description:
all placebo patients who were re-randomized to secukinumab 150 mg at re-randomization

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
150 mg

Arm title	Placebo - AIN457 300mg

Arm description:
all placebo patients who were re-randomized to AIN457 300 mg at re-randomization

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
300 mg

Arm title	Placebo

Arm description:
placebo AIN457 (2 sc injections) once weekly for 5 weeks, followed by dosing every 4 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:
placebo

Number of subjects in period 2	AIN457 150mg	AIN457 300 mg	Placebo - AIN457 150 mg
Started	63	64	31
Completed	24	44	17
Not completed	39	20	14
Adverse event, serious fatal	1	-	-
Physician decision	1	1	-
Consent withdrawn by subject	10	5	6
Adverse event, non-fatal	9	6	4
study terminated by sponsor	-	1	-
Lost to follow-up	2	-	-
Lack of efficacy	12	5	3
Protocol deviation	2	-	-
non-compliance with study treatment	2	2	1

Number of subjects in period 2	Placebo - AIN457 300mg	Placebo
Started	31	1
Completed	20	0
Not completed	11	1
Adverse event, serious fatal	-	-
Physician decision	-	-
Consent withdrawn by subject	5	-
Adverse event, non-fatal	3	1
study terminated by sponsor	1	-
Lost to follow-up	-	-
Lack of efficacy	1	-
Protocol deviation	-	-
non-compliance with study treatment	1	-

Period 3	
Period 3 title	Follow-up Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms	
Are arms mutually exclusive?	No

Arm title	Any AIN457 150mg

Arm description:

AIN457 150mg sub-cutaneous (s.c.) injection plus a placebo AIN457 s.c. injection once weekly for 5 weeks followed by dosing every 4 weeks

Arm type	Experimental
Investigational medicinal product name	secukinumab 150 mg
Investigational medicinal product code	AIN457
Other name	secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

150 mg

Arm title	Any AIN457 300 mg

Arm description:

AIN457 300 mg (2 s.c. injections of the 150 mg dose) once weekly for 5 weeks followed by dosing every 4 weeks

Arm type	Experimental
Investigational medicinal product name	secukinumab 300 mg
Investigational medicinal product code	AIN457
Other name	secukinumab
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

300 mg

Arm title	Placebo

Arm description:

placebo AIN457 (2 sc injections) once weekly for 5 weeks, followed by dosing every 4 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	Placebo
Other name	Placebo
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

placebo

Number of subjects in period 3	Any AIN457 150mg	Any AIN457 300 mg	Placebo
Started	77	84	3
Completed	67	82	3
Not completed	10	2	0
Consent withdrawn by subject	4	1	-
Physician decision	1	-	-
Adverse event, non-fatal	2	-	-
Lost to follow-up	2	-	-
Lack of efficacy	1	1	-

Baseline characteristics

Reporting groups	
Reporting group title	AIN457 150mg
Reporting group description:	
AIN457 150mg sub-cutaneous (s.c.) injection plus a placebo AIN457 s.c. injection once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	AIN457 300 mg
Reporting group description:	
AIN457 300 mg (2 s.c. injections of the 150 mg dose) once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	Placebo
Reporting group description:	
placebo AIN457 (2 sc injections) once weekly for 5 weeks, followed by dosing every 4 weeks.	

Reporting group values	AIN457 150mg	AIN457 300 mg	Placebo
Number of subjects	68	69	68
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	56	60	60
From 65-84 years	12	9	8
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	52.4	48.8	50.9
standard deviation	± 12.56	± 14.21	± 12.95
Gender, Male/Female Units: Subjects			
Female	28	31	34
Male	40	38	34

Reporting group values	Total		
Number of subjects	205		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		

Adults (18-64 years)	176		
From 65-84 years	29		
85 years and over	0		
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: Subjects			
Female	93		
Male	112		

Subject analysis sets

Subject analysis set title	Placebo - AIN457 300 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
all placebo patients who were re-randomized to secukinumab 300 mg at re-randomization.	
Subject analysis set title	Placebo - AIN 150mg
Subject analysis set type	Full analysis
Subject analysis set description:	
all placebo patients who were re-randomized to AIN457 150 mg at re-randomization	

Reporting group values	Placebo - AIN457 300 mg	Placebo - AIN 150mg	
Number of subjects	31	31	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	29	27	
From 65-84 years	2	4	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean			
standard deviation	±	±	
Gender, Male/Female			
Units: Subjects			
Female			
Male			

End points

End points reporting groups

Reporting group title	AIN457 150mg
Reporting group description:	
AIN457 150mg sub-cutaneous (s.c.) injection plus a placebo AIN457 s.c. injection once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	AIN457 300 mg
Reporting group description:	
AIN457 300 mg (2 s.c. injections of the 150 mg dose) once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	Placebo
Reporting group description:	
placebo AIN457 (2 sc injections) once weekly for 5 weeks, followed by dosing every 4 weeks.	
Reporting group title	AIN457 150mg
Reporting group description:	
AIN457 150mg sub-cutaneous (s.c.) injection plus a placebo AIN457 s.c. injection once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	AIN457 300 mg
Reporting group description:	
AIN457 300 mg (2 s.c. injections of the 150 mg dose) once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	Placebo - AIN457 150 mg
Reporting group description:	
all placebo patients who were re-randomized to secukinumab 150 mg at re-randomization	
Reporting group title	Placebo - AIN457 300mg
Reporting group description:	
all placebo patients who were re-randomized to AIN457 300 mg at re-randomization	
Reporting group title	Placebo
Reporting group description:	
placebo AIN457 (2 sc injections) once weekly for 5 weeks, followed by dosing every 4 weeks.	
Reporting group title	Any AIN457 150mg
Reporting group description:	
AIN457 150mg sub-cutaneous (s.c.) injection plus a placebo AIN457 s.c. injection once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	Any AIN457 300 mg
Reporting group description:	
AIN457 300 mg (2 s.c. injections of the 150 mg dose) once weekly for 5 weeks followed by dosing every 4 weeks	
Reporting group title	Placebo
Reporting group description:	
placebo AIN457 (2 sc injections) once weekly for 5 weeks, followed by dosing every 4 weeks.	
Subject analysis set title	Placebo - AIN457 300 mg
Subject analysis set type	Full analysis
Subject analysis set description:	
all placebo patients who were re-randomized to secukinumab 300 mg at re-randomization.	
Subject analysis set title	Placebo - AIN 150mg
Subject analysis set type	Full analysis
Subject analysis set description:	
all placebo patients who were re-randomized to AIN457 150 mg at re-randomization	

Primary: Percentages of participants with palmoplantar Investigator Global Assessmnet (ppIGA) 0 or 1 response after 16 weeks of treatment

End point title	Percentages of participants with palmoplantar Investigator Global Assessmnet (ppIGA) 0 or 1 response after 16 weeks of treatment

End point description:

palmoplantar Investigator's Global Assessment (ppIGA) response after 16 weeks of treatment. To be considered a ppIGA responder at Week 16, a subject must have ppIGA of 0 or 1 at Week 16 and a reduction of at least 2 points on the ppIGA scale from baseline.

End point type	Primary

End point timeframe:

Week 16

End point values	AIN457 150mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	68	68	
Units: Percentages of participants				
number (not applicable)	22	33.3	1.5	

Statistical analyses

Statistical analysis title	Statistical analysis of ppIGA 0 or 1 response

Statistical analysis description:

Data at Week 16 was analyzed using the stratified Cochran-Mantel-Haenszel-test. The test was stratified by body-weight category (<90 kg or ≥90 kg).

Comparison groups	AIN457 150mg v Placebo
Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	19.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.4
upper limit	154.6

Statistical analysis title	Statistical analysis of ppIGA 0 or 1 response

Statistical analysis description:

Data at Week 16 was analyzed using the stratified Cochran-Mantel-Haenszel-test. The test was stratified by body-weight category (<90 kg or ≥90 kg).

Comparison groups	AIN457 300 mg v Placebo

Number of subjects included in analysis	136
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	29.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.1
upper limit	211.9

Secondary: Percentages of participants with palmoplantar Investigator Global Assessment (ppIGA) 0 or 1 response - treatment period I

End point title	Percentages of participants with palmoplantar Investigator Global Assessment (ppIGA) 0 or 1 response - treatment period I

End point description:

ppIGA: Palmoplantar Ivestigator’s Global Assessment. The IGA mod 2011 rating scale: The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe. Based on this scale, a patient was considered as an IGA 0 or 1 responder if they achieved a score of 0 or 1 and improved by at least 2 points on the IGA scale at a given time point compared to their score at randomization (baseline).

End point type	Secondary

End point timeframe:

Week 1, week 2, week 4, week, 8, week 12, week 16

End point values	AIN457 150mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	69	68	
Units: Percentages of participants				
number (not applicable)				
Week 1	1.5	1.4	0	
Week 2	1.5	7.2	0	
Week 4	4.4	8.7	0	
Week 8	17.6	26.1	0	
Week 12	20.6	33.3	1.5	
Week 16	22.1	33.3	1.5	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with ppIGA 0 or 1 response (observed cases) - treatment period II

End point title	Percentages of subjects with ppIGA 0 or 1 response (observed cases) - treatment period II

End point description:

ppIGA: Palmoplantar Ivestigator’s Global Assessment. The IGA mod 2011 rating scale: The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe. Based on this scale, a patient was considered as an IGA 0 or 1 responder if they achieved a score of 0 or 1 and improved by at least 2 points on the IGA scale at a given time point compared to their score at randomization (baseline).

End point type	Secondary

End point timeframe:

Week 20, Week 28, Week 32, Week 64, Week 132

End point values	AIN457 150mg	AIN457 300 mg	Placebo	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	68	69	1	31
Units: Percentages of participants				
number (not applicable)				
Week 20	32.4	33.3	0.0	9.7
Week 28	29.4	44.9	100.0	51.6
Week 32	29.4	42.0	0.0	41.9
Week 64	26.5	46.4	0.0	48.4
Week 132	22.1	27.5	0.0	35.5

End point values	Placebo - AIN 150mg			
Subject group type	Subject analysis set			
Number of subjects analysed	31			
Units: Percentages of participants				
number (not applicable)				
Week 20	12.9			
Week 28	32.3			
Week 32	35.5			
Week 64	29.0			
Week 132	12.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with ppIGA 0 or 1 response (observed cases) - entire treatment period

End point title	Percentages of subjects with ppIGA 0 or 1 response (observed cases) - entire treatment period

End point description:

ppIGA: Palmoplantar Ivestigator’s Global Assessment. The IGA mod 2011 rating scale: The IGA mod 2011 scale is static, i.e. it referred exclusively to the participant's disease at the time of the assessment, and did not compare with any of the participant's previous disease states at previous visits. The scores are: 0 = clear, 1 = almost clear, 2 = mild, 3 = moderate and 4 = severe. Based on this scale, a patient was considered as an IGA 0 or 1 responder if they achieved a score of 0 or 1 and improved by at least 2 points on the IGA scale at a given time point compared to their score at randomization (baseline).

End point type	Secondary

End point timeframe:

Week 16, Week 24, Week 28, Week 80

End point values	AIN457 150mg	AIN457 300 mg	Placebo	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	68	69	6	31
Units: Percentages of participants				
number (not applicable)				
Week 16	23.4	37.7	25.0	0
Week 24	40.7	44.1	100.0	36.7
Week 28	34.5	50.8	0	48.3
Week 80	41.7	65.3	0	68.2

End point values	Placebo - AIN 150mg			
Subject group type	Subject analysis set			
Number of subjects analysed	31			
Units: Percentages of participants				
number (not applicable)				
Week 16	0			
Week 24	20.0			
Week 28	20.0			
Week 80	45.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for palmoplantar Psoriasis Area and Severity Index (ppPASI) score -treatment period I

End point title	Absolute change from baseline for palmoplantar Psoriasis Area and Severity Index (ppPASI) score -treatment period I

End point description:

Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring

(head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 75, 90 and 100 were defined as participants achieving ≥ 75%, 90% or 100%

End point type	Secondary

End point timeframe:

Week 1, Week 2, Week 4, Week 8, Week 12, Week 16

End point values	AIN457 150mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	68	69	68	
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 1	-1.13 (± 4.797)	-2.22 (± 4.334)	-0.85 (± 3.355)	
Week 2	-3.11 (± 7.669)	-5.32 (± 6.120)	-1.90 (± 5.434)	
Week 4	-6.69 (± 9.890)	-9.18 (± 9.734)	-3.95 (± 7.424)	
Week 8	-9.74 (± 12.779)	-11.30 (± 11.954)	-3.22 (± 8.316)	
Week 12	-10.15 (± 14.409)	-12.83 (± 12.286)	-3.07 (± 8.479)	
Week 16	-9.41 (± 15.984)	-13.35 (± 12.941)	-2.43 (± 8.527)	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for palmoplantar Psoriasis Area and Severity Index (ppPASI) score (observed cases) - entire treatment set

End point title	Absolute change from baseline for palmoplantar Psoriasis Area and Severity Index (ppPASI) score (observed cases) - entire treatment set

End point description:

Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, arms, trunk, legs; each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area* area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 75, 90 and 100 were defined as participants achieving ≥ 75%, 90% or 100%

End point type	Secondary

End point timeframe:

Week 16, Week 32, Week 80, Week 132

End point values	AIN457 150mg	AIN457 300 mg	Placebo	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	68	69	6	31
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 16	-8.97 (± 15.624)	-12.67 (± 12.074)	-7.15 (± 4.479)	-3.11 (± 7.983)
Week 32	-16.29 (± 14.307)	-17.43 (± 13.104)	-11.40 (± 999)	-15.09 (± 12.625)
Week 80	-18.05 (± 15.232)	-19.27 (± 14.258)	-999 (± 999)	-16.70 (± 10.441)
Week 132	-16.74 (± 14.658)	-19.16 (± 11.688)	-999 (± 999)	-13.82 (± 5.844)

End point values	Placebo - AIN 150mg			
Subject group type	Subject analysis set			
Number of subjects analysed	31			
Units: Units on a scale				
arithmetic mean (standard deviation)				
Week 16	-1.57 (± 8.880)			
Week 32	-15.49 (± 11.570)			
Week 80	-13.71 (± 14.560)			
Week 132	-17.07 (± 11.728)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants developing anti-secukinumab antibodies

End point title	Number of participants developing anti-secukinumab

End point description:

To investigate the development of immunogenicity against secukinumab

End point type	Secondary

End point timeframe:

Over time up to week 132

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: There was no statistics involved with this endpoint.

End point values	AIN457 150mg	AIN457 300 mg	Placebo - AIN457 300 mg	Placebo - AIN 150mg
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	68	69	31	31
Units: Number of participants	2	2	3	2

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Timeframe for AE	
Adverse event reporting additional description:	
AE additional description	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.1

Reporting groups	
Reporting group title	Any AIN457 150 mg
Reporting group description:	
Any AIN457 150 mg	
Reporting group title	Any AIN457 300 mg
Reporting group description:	
Any AIN457 300 mg	
Reporting group title	Placebo
Reporting group description:	
Placebo	
Reporting group title	Any AIN457 dose
Reporting group description:	
Any AIN457 dose	

Serious adverse events	Any AIN457 150 mg	Any AIN457 300 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 99 (19.19%)	13 / 100 (13.00%)	2 / 68 (2.94%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leiomyoma			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (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
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Social circumstances			
Miscarriage of partner			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
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			
Pneumothorax spontaneous			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Completed suicide			

subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (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
Injury, poisoning and procedural complications			
Fibula fracture			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Fracture displacement			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral nerve injury			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Tendon injury			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Coronary artery occlusion			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Hypoaesthesia			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar radiculopathy			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Paraesthesia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyneuropathy			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient global amnesia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (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
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Small intestinal obstruction			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	2 / 99 (2.02%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Psoriatic arthropathy			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (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
Spinal column stenosis			

subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (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
Tenosynovitis stenosans			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis of male external genital organ			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (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	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective keratitis			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (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
Pyelonephritis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	1 / 68 (1.47%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electrolyte imbalance			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Any AIN457 dose		
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 199 (16.08%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Leiomyoma			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Uterine leiomyoma			

subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Social circumstances			
Miscarriage of partner			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postmenopausal haemorrhage			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumothorax spontaneous			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Completed suicide			

subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Injury, poisoning and procedural complications				
Fibula fracture				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Foot fracture				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fracture displacement				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peripheral nerve injury				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendon injury				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Angina pectoris				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Coronary artery occlusion			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lumbar radiculopathy			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Polyneuropathy			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient global amnesia			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Small intestinal obstruction			
subjects affected / exposed	0 / 199 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal pain			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Psoriatic arthropathy			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Spinal column stenosis			

subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tenosynovitis stenosans				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Cellulitis of male external genital organ				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infective keratitis				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 199 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 199 (0.50%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Skin infection				

subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Any AIN457 150 mg	Any AIN457 300 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	75 / 99 (75.76%)	68 / 100 (68.00%)	30 / 68 (44.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Melanocytic naevus			
subjects affected / exposed	2 / 99 (2.02%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	2	1	0
Seborrhoeic keratosis			
subjects affected / exposed	4 / 99 (4.04%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	4	0	0
Vascular disorders			

Haematoma			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Hypertension			
subjects affected / exposed	5 / 99 (5.05%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	5	3	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Fatigue			
subjects affected / exposed	4 / 99 (4.04%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	4	1	0
Influenza like illness			
subjects affected / exposed	1 / 99 (1.01%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	1	3	0
Injection site haematoma			
subjects affected / exposed	2 / 99 (2.02%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	2	1	0
Injection site reaction			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Oedema peripheral			
subjects affected / exposed	5 / 99 (5.05%)	4 / 100 (4.00%)	0 / 68 (0.00%)
occurrences (all)	5	4	0
Peripheral swelling			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	1 / 68 (1.47%)
occurrences (all)	2	0	1
Pyrexia			
subjects affected / exposed	4 / 99 (4.04%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	5	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 99 (3.03%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	3	2	1
Dyspnoea			

subjects affected / exposed	3 / 99 (3.03%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	3	1	0
Oropharyngeal pain			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	2	2	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Depression			
subjects affected / exposed	2 / 99 (2.02%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	2	1	0
Investigations			
Weight increased			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Muscle strain			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	2	3	0
Procedural pain			
subjects affected / exposed	1 / 99 (1.01%)	4 / 100 (4.00%)	0 / 68 (0.00%)
occurrences (all)	1	6	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	2 / 68 (2.94%)
occurrences (all)	0	1	8
Headache			
subjects affected / exposed	10 / 99 (10.10%)	11 / 100 (11.00%)	6 / 68 (8.82%)
occurrences (all)	15	14	16
Paraesthesia			
subjects affected / exposed	2 / 99 (2.02%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	2	1	0

Eye disorders			
Blepharitis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	2	2	1
Constipation			
subjects affected / exposed	3 / 99 (3.03%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	3	0	0
Dental caries			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	1 / 68 (1.47%)
occurrences (all)	2	0	1
Diarrhoea			
subjects affected / exposed	4 / 99 (4.04%)	4 / 100 (4.00%)	0 / 68 (0.00%)
occurrences (all)	4	5	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 99 (3.03%)	3 / 100 (3.00%)	1 / 68 (1.47%)
occurrences (all)	3	3	1
Nausea			
subjects affected / exposed	3 / 99 (3.03%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	6	1	0
Toothache			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	2	3	0
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	2 / 99 (2.02%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	2	1	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 99 (0.00%)	1 / 100 (1.00%)	2 / 68 (2.94%)
occurrences (all)	0	1	2
Actinic keratosis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	3	0	0

Dermatitis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Dermatitis contact			
subjects affected / exposed	3 / 99 (3.03%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	3	0	0
Eczema			
subjects affected / exposed	4 / 99 (4.04%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	4	2	1
Pruritus			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	2	2	1
Psoriasis			
subjects affected / exposed	12 / 99 (12.12%)	11 / 100 (11.00%)	4 / 68 (5.88%)
occurrences (all)	12	12	4
Pustular psoriasis			
subjects affected / exposed	0 / 99 (0.00%)	0 / 100 (0.00%)	2 / 68 (2.94%)
occurrences (all)	0	0	2
Rash			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	4	2	0
Skin mass			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Urticaria			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	2	2	0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	3 / 99 (3.03%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	3	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 99 (5.05%)	4 / 100 (4.00%)	4 / 68 (5.88%)
occurrences (all)	6	5	5
Arthritis			

subjects affected / exposed	3 / 99 (3.03%)	0 / 100 (0.00%)	1 / 68 (1.47%)
occurrences (all)	3	0	1
Back pain			
subjects affected / exposed	2 / 99 (2.02%)	10 / 100 (10.00%)	2 / 68 (2.94%)
occurrences (all)	2	10	2
Muscle spasms			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	2	2	0
Musculoskeletal pain			
subjects affected / exposed	4 / 99 (4.04%)	3 / 100 (3.00%)	2 / 68 (2.94%)
occurrences (all)	4	3	2
Myalgia			
subjects affected / exposed	4 / 99 (4.04%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	6	1	0
Osteoarthritis			
subjects affected / exposed	4 / 99 (4.04%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	4	1	0
Pain in extremity			
subjects affected / exposed	5 / 99 (5.05%)	1 / 100 (1.00%)	1 / 68 (1.47%)
occurrences (all)	5	1	1
Psoriatic arthropathy			
subjects affected / exposed	1 / 99 (1.01%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	1	3	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	4	2	1
Cellulitis			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	2	3	0
Conjunctivitis			
subjects affected / exposed	2 / 99 (2.02%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	2	3	0
Folliculitis			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	3	0	0

Gastroenteritis			
subjects affected / exposed	5 / 99 (5.05%)	4 / 100 (4.00%)	0 / 68 (0.00%)
occurrences (all)	5	4	0
Genital infection fungal			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Impetigo			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Influenza			
subjects affected / exposed	4 / 99 (4.04%)	7 / 100 (7.00%)	4 / 68 (5.88%)
occurrences (all)	4	9	4
Localised infection			
subjects affected / exposed	0 / 99 (0.00%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	0	3	0
Nasopharyngitis			
subjects affected / exposed	14 / 99 (14.14%)	8 / 100 (8.00%)	4 / 68 (5.88%)
occurrences (all)	20	19	4
Oral candidiasis			
subjects affected / exposed	0 / 99 (0.00%)	5 / 100 (5.00%)	0 / 68 (0.00%)
occurrences (all)	0	5	0
Oral herpes			
subjects affected / exposed	3 / 99 (3.03%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	4	4	1
Pharyngitis			
subjects affected / exposed	3 / 99 (3.03%)	6 / 100 (6.00%)	0 / 68 (0.00%)
occurrences (all)	3	9	0
Rhinitis			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	0 / 68 (0.00%)
occurrences (all)	2	2	0
Sinusitis			
subjects affected / exposed	1 / 99 (1.01%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	1	3	0
Skin infection			
subjects affected / exposed	2 / 99 (2.02%)	2 / 100 (2.00%)	1 / 68 (1.47%)
occurrences (all)	3	2	1

Tinea pedis			
subjects affected / exposed	5 / 99 (5.05%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	6	1	0
Tonsillitis			
subjects affected / exposed	1 / 99 (1.01%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	1	3	0
Tooth abscess			
subjects affected / exposed	2 / 99 (2.02%)	0 / 100 (0.00%)	0 / 68 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	10 / 99 (10.10%)	20 / 100 (20.00%)	3 / 68 (4.41%)
occurrences (all)	16	27	3
Urinary tract infection			
subjects affected / exposed	3 / 99 (3.03%)	7 / 100 (7.00%)	0 / 68 (0.00%)
occurrences (all)	3	7	0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 99 (2.02%)	1 / 100 (1.00%)	0 / 68 (0.00%)
occurrences (all)	3	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 99 (1.01%)	0 / 100 (0.00%)	2 / 68 (2.94%)
occurrences (all)	1	0	2
Dyslipidaemia			
subjects affected / exposed	1 / 99 (1.01%)	3 / 100 (3.00%)	0 / 68 (0.00%)
occurrences (all)	1	3	0

Non-serious adverse events	Any AIN457 dose		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	143 / 199 (71.86%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	2 / 199 (1.01%)		
occurrences (all)	2		
Melanocytic naevus			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences (all)	3		
Seborrhoeic keratosis			

subjects affected / exposed occurrences (all)	4 / 199 (2.01%) 4		
Vascular disorders Haematoma subjects affected / exposed occurrences (all) Hypertension subjects affected / exposed occurrences (all)	 2 / 199 (1.01%) 2 8 / 199 (4.02%) 8		
General disorders and administration site conditions Chills subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Influenza like illness subjects affected / exposed occurrences (all) Injection site haematoma subjects affected / exposed occurrences (all) Injection site reaction subjects affected / exposed occurrences (all) Oedema peripheral subjects affected / exposed occurrences (all) Peripheral swelling subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all)	 2 / 199 (1.01%) 2 5 / 199 (2.51%) 5 4 / 199 (2.01%) 4 3 / 199 (1.51%) 3 2 / 199 (1.01%) 2 9 / 199 (4.52%) 9 2 / 199 (1.01%) 2 5 / 199 (2.51%) 6		
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	5 / 199 (2.51%) 5		
Dyspnoea subjects affected / exposed occurrences (all)	4 / 199 (2.01%) 4		
Oropharyngeal pain subjects affected / exposed occurrences (all)	4 / 199 (2.01%) 4		
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	2 / 199 (1.01%) 2		
Depression subjects affected / exposed occurrences (all)	3 / 199 (1.51%) 3		
Investigations Weight increased subjects affected / exposed occurrences (all)	2 / 199 (1.01%) 2		
Injury, poisoning and procedural complications Arthropod bite subjects affected / exposed occurrences (all)	2 / 199 (1.01%) 2		
Muscle strain subjects affected / exposed occurrences (all)	4 / 199 (2.01%) 5		
Procedural pain subjects affected / exposed occurrences (all)	5 / 199 (2.51%) 7		
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 199 (0.50%) 1		
Headache			

subjects affected / exposed	21 / 199 (10.55%)		
occurrences (all)	29		
Paraesthesia			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences (all)	3		
Eye disorders			
Blepharitis			
subjects affected / exposed	2 / 199 (1.01%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Constipation			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences (all)	3		
Dental caries			
subjects affected / exposed	2 / 199 (1.01%)		
occurrences (all)	2		
Diarrhoea			
subjects affected / exposed	8 / 199 (4.02%)		
occurrences (all)	9		
Gastrooesophageal reflux disease			
subjects affected / exposed	6 / 199 (3.02%)		
occurrences (all)	6		
Nausea			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	7		
Toothache			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	5		
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			

Acne			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences (all)	1		
Actinic keratosis			
subjects affected / exposed	2 / 199 (1.01%)		
occurrences (all)	3		
Dermatitis			
subjects affected / exposed	2 / 199 (1.01%)		
occurrences (all)	2		
Dermatitis contact			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences (all)	3		
Eczema			
subjects affected / exposed	6 / 199 (3.02%)		
occurrences (all)	6		
Pruritus			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Psoriasis			
subjects affected / exposed	23 / 199 (11.56%)		
occurrences (all)	24		
Pustular psoriasis			
subjects affected / exposed	0 / 199 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	6		
Skin mass			
subjects affected / exposed	2 / 199 (1.01%)		
occurrences (all)	2		
Urticaria			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Renal and urinary disorders			
Nephrolithiasis			

subjects affected / exposed	5 / 199 (2.51%)		
occurrences (all)	5		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	9 / 199 (4.52%)		
occurrences (all)	11		
Arthritis			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences (all)	3		
Back pain			
subjects affected / exposed	12 / 199 (6.03%)		
occurrences (all)	12		
Muscle spasms			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Musculoskeletal pain			
subjects affected / exposed	7 / 199 (3.52%)		
occurrences (all)	7		
Myalgia			
subjects affected / exposed	5 / 199 (2.51%)		
occurrences (all)	7		
Osteoarthritis			
subjects affected / exposed	5 / 199 (2.51%)		
occurrences (all)	5		
Pain in extremity			
subjects affected / exposed	6 / 199 (3.02%)		
occurrences (all)	6		
Psoriatic arthropathy			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Infections and infestations			
Bronchitis			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	6		
Cellulitis			

subjects affected / exposed	4 / 199 (2.01%)			
occurrences (all)	5			
Conjunctivitis				
subjects affected / exposed	5 / 199 (2.51%)			
occurrences (all)	5			
Folliculitis				
subjects affected / exposed	2 / 199 (1.01%)			
occurrences (all)	3			
Gastroenteritis				
subjects affected / exposed	9 / 199 (4.52%)			
occurrences (all)	9			
Genital infection fungal				
subjects affected / exposed	2 / 199 (1.01%)			
occurrences (all)	2			
Impetigo				
subjects affected / exposed	2 / 199 (1.01%)			
occurrences (all)	2			
Influenza				
subjects affected / exposed	11 / 199 (5.53%)			
occurrences (all)	13			
Localised infection				
subjects affected / exposed	3 / 199 (1.51%)			
occurrences (all)	3			
Nasopharyngitis				
subjects affected / exposed	22 / 199 (11.06%)			
occurrences (all)	39			
Oral candidiasis				
subjects affected / exposed	5 / 199 (2.51%)			
occurrences (all)	5			
Oral herpes				
subjects affected / exposed	5 / 199 (2.51%)			
occurrences (all)	8			
Pharyngitis				
subjects affected / exposed	9 / 199 (4.52%)			
occurrences (all)	12			
Rhinitis				

subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Sinusitis			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Skin infection			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	5		
Tinea pedis			
subjects affected / exposed	6 / 199 (3.02%)		
occurrences (all)	7		
Tonsillitis			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		
Tooth abscess			
subjects affected / exposed	2 / 199 (1.01%)		
occurrences (all)	2		
Upper respiratory tract infection			
subjects affected / exposed	30 / 199 (15.08%)		
occurrences (all)	43		
Urinary tract infection			
subjects affected / exposed	10 / 199 (5.03%)		
occurrences (all)	10		
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 199 (1.51%)		
occurrences (all)	4		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 199 (0.50%)		
occurrences (all)	1		
Dyslipidaemia			
subjects affected / exposed	4 / 199 (2.01%)		
occurrences (all)	4		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 January 2015	The purpose of Amendment 1 was to provide continued treatment to patients for an additional 52 weeks (overall up to 132 weeks). This extension of treatment allowed for safety, tolerability, and efficacy data to be collected from the participating patients over a longer period of time.
12 March 2015	The purpose of Amendment 2 was to allow, on ethical grounds, patients who completed the Week 80 visit before implementation of Amendment 1 at sites to continue receiving study medication as the study treatment was not yet commercially available in all participating countries.

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.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/CtrdWeb/home.novfor complete trial results.

Notes: