Clinical trial results:
A randomized, double-blind, placebo-controlled, multicenter study of subcutaneous secukinumab in autoinjectors to demonstrate efficacy after twelve weeks of treatment, and to assess the safety, tolerability, usability and long-term efficacy in subjects with chronic plaque-type psoriasis: Judging the Efficacy of SecUkinumab in Patients with Psoriasis using AutoiNjector: a Clinical Trial Evaluating Treatment REsults (JUNCTURE)

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	2012-002609-22
Trial protocol	DE EE
Global end of trial date	27 October 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	CAIN457A2309

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01636687
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
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,

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	27 October 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the efficacy of AI-administered secukinumab (150 mg and 300 mg) in patients with moderate to severe chronic plaque-type psoriasis with respect to both PASI 75 and IGA mod 2011 0 or 1 response (co-primary endpoints) at Week 12 compared to placebo.

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	17 October 2012
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	Canada: 35
Country: Number of subjects enrolled	Estonia: 22
Country: Number of subjects enrolled	France: 24
Country: Number of subjects enrolled	Germany: 66
Country: Number of subjects enrolled	United States: 35
Worldwide total number of subjects	182
EEA total number of subjects	112

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)	166
From 65 to 84 years	16
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 220 patients were screened at 39 study centers, and 182 patients were randomized at 38 study centers to 3 balanced groups.

Period 1

Period 1 title	Induction Period
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 150 mg

Arm description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.

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:

Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.

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 secukinumab (2 s.c. injections) at each dosing

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 150 mg	AIN457 300 mg	Placebo
Started	61	60	61
Completed	58	60	59
Not completed	3	0	2
Physician decision	1	-	-
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	1	-	1
Lack of efficacy	-	-	1

Period 2

Period 2 title	Maintenance Period
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 150 mg

Arm description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.

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:

Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.

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:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.

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:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study.

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 secukinumab (2 s.c. injections) at each dosing

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 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg
Started	58	60	28
Completed	50	58	26
Not completed	8	2	2
Consent withdrawn by subject	2	-	2
Physician decision	-	-	-
Adverse event, non-fatal	1	-	-
Lost to follow-up	1	1	-
Lack of efficacy	4	1	-

Number of subjects in period 2	Placebo - AIN457 300mg	Placebo
Started	28	3
Completed	28	1
Not completed	0	2
Consent withdrawn by subject	-	-
Physician decision	-	1
Adverse event, non-fatal	-	-
Lost to follow-up	-	1
Lack of efficacy	-	-

Period 3

Period 3 title	Extension Period
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 150 mg

Arm description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.

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:

Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.

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:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.

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:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study.

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

Number of subjects in period 3[1]	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg
Started	47	54	25
Completed	0	0	0
Not completed	47	54	25
technical problems	-	1	2
Physician decision	1	-	-
Consent withdrawn by subject	1	-	1
Adverse event, non-fatal	4	3	2
study terminated by sponsor	33	50	17
Lost to follow-up	1	-	1

Lack of efficacy	7	-	2

Number of subjects in period 3[1]	Placebo - AIN457 300mg
Started	28
Completed	0
Not completed	28
technical problems	1
Physician decision	1
Consent withdrawn by subject	1
Adverse event, non-fatal	1
study terminated by sponsor	23
Lost to follow-up	-
Lack of efficacy	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Not all patients were eligible or willing to enter the extension period after completing the preceding period (maintenance). This is the reason why the numbers are not equal.

Period 4

Period 4 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	AIN457 150 mg

Arm description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.

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:

Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.

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:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.

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:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study.

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 secukinumab (2 s.c. injections) at each dosing

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 4	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg
Started	38	45	21
Completed	37	45	21
Not completed	1	0	0
Consent withdrawn by subject	1	-	-

Number of subjects in period 4	Placebo - AIN457 300mg	Placebo
Started	20	2
Completed	20	1
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

Reporting groups	
Reporting group title	AIN457 150 mg
Reporting group description:	
Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.	
Reporting group title	AIN457 300 mg
Reporting group description:	
Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.	
Reporting group title	Placebo
Reporting group description:	
placebo secukinumab (2 s.c. injections) at each dosing	

Reporting group values	AIN457 150 mg	AIN457 300 mg	Placebo
Number of subjects	61	60	61
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	43.9	46.6	43.7
standard deviation	± 14.41	± 14.23	± 12.74
Gender, Male/Female Units: Subjects			
Female	20	14	23
Male	41	46	38

Reporting group values	Total		
Number of subjects	182		
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: Subjects			
Female	57		
Male	125		

End points

End points reporting groups

Reporting group title	AIN457 150 mg
Reporting group description:	
Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.	
Reporting group title	AIN457 300 mg
Reporting group description:	
Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.	
Reporting group title	Placebo
Reporting group description:	
placebo secukinumab (2 s.c. injections) at each dosing	
Reporting group title	AIN457 150 mg
Reporting group description:	
Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.	
Reporting group title	AIN457 300 mg
Reporting group description:	
Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.	
Reporting group title	Placebo - AIN457 150 mg
Reporting group description:	
Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.	
Reporting group title	Placebo - AIN457 300mg
Reporting group description:	
Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study.	
Reporting group title	Placebo
Reporting group description:	
placebo secukinumab (2 s.c. injections) at each dosing	
Reporting group title	AIN457 150 mg
Reporting group description:	
Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.	
Reporting group title	AIN457 300 mg
Reporting group description:	
Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.	
Reporting group title	Placebo - AIN457 150 mg
Reporting group description:	
Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.	
Reporting group title	Placebo - AIN457 300mg
Reporting group description:	
Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study.	
Reporting group title	AIN457 150 mg
Reporting group description:	
Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.	
Reporting group title	AIN457 300 mg

Reporting group description:

Patients received two secukinumab 150 mg s.c. injections at each dosing. In the open label phase only two 150 mg s.c. injections at each dosing.

Reporting group title	Placebo - AIN457 150 mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.

Reporting group title	Placebo - AIN457 300mg

Reporting group description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 300 mg for the remainder of the study.

Reporting group title	Placebo

Reporting group description:

placebo secukinumab (2 s.c. injections) at each dosing

Subject analysis set title	Placebo - AIN457 300 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.

Subject analysis set title	AIN 150 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients received one secukinumab 150 mg s.c. injection plus one placebo secukinumab s.c. injection at each dosing. In the open label phase only one 150 mg s.c. injection at each dosing.

Subject analysis set title	Placebo-AIN 150 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Patients were on Placebo in induction phase and if they were PASI 75 non responders at week 12, were re randomized to AIN457 150 mg for the remainder of the study.

Primary: Psoriasis Area and Severity Index (PASI) 75 response and Investigators' Global Assessment (IGA) mod 2011 0 or 1 response.

End point title	Psoriasis Area and Severity Index (PASI) 75 response and Investigators' Global Assessment (IGA) mod 2011 0 or 1 response.

End point description:

Efficacy of secukinumab compared to placebo in subjects with moderate to severe chronic plaque-type psoriasis. PASI score was based on assessment of the head, trunk, upper limbs and lower limbs for erythema, thickening (plaque elevation, induration), and scaling (desquamation). PASI scores can range from 0, corresponding to no signs of psoriasis, up to a theoretical maximum of 72.0. PASI-based secondary variables included absolute PASI score, response rates for PASI 75. PASI 50 and PASI 90 were defined as ≥ 50% and ≥ 90% improvement from Baseline in PASI score, respectively, while PASI 100 response corresponded to complete clearing of psoriasis (PASI = 0). IGA mod 2011 was used to evaluate the overall severity of psoriatic disease, with scores ranging from 0 (clear) to 4 (severe). Treatment success was defined as achievement of IGA mod 2011 0 or 1 score.

End point type	Primary

End point timeframe:

12 weeks

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	60	60	61	
Units: Percentages of participants				
number (not applicable)				
PASI 75	71.7	86.7	3.3	
IGA 0/1	53.3	73.3	0.0	

Statistical analyses

Statistical analysis title	Efficacy of secukinumab compared to placebo
Statistical analysis description: Response criterion: IGA 0/1	
Comparison groups	AIN457 150 mg v Placebo
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	53.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	36.6
upper limit	67.7

Statistical analysis title	Efficacy of secukinumab compared to placebo
Statistical analysis description: Response Criterion: IGA 0/1	
Comparison groups	AIN457 300 mg v Placebo
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	73.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	58.8
upper limit	83.9

Statistical analysis title	Efficacy of secukinumab compared to placebo
Statistical analysis description: Response criterion: PASI 75	
Comparison groups	AIN457 150 mg v Placebo
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	68.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.1
upper limit	79.8

Statistical analysis title	Efficacy of secukinumab compared to placebo
Statistical analysis description: Response criterion: PASI 75	
Comparison groups	AIN457 300 mg v Placebo
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Fisher exact
Parameter estimate	Risk difference (RD)
Point estimate	83.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.7
upper limit	91.7

Secondary: Percentages of subjects with successful self-administration of study drug at week 1

End point title	Percentages of subjects with successful self-administration of study drug at week 1
End point description: To assess the subject’s ability to follow instructions for use with the secukinumab autoinjector	
End point type	Secondary
End point timeframe: Week 1	

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	60	
Units: Percentages of participants	100	100	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects with possible use-related hazards

End point title	Percentage of subjects with possible use-related hazards

End point description:

To assess potential use-related hazards with the secukinumab autoinjector for the subject.

End point type	Secondary

End point timeframe:

Week 1

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	61	
Units: Percentages of participants				
number (not applicable)				
Needle stick in a critical area	0	0	0	
Needle stick in non-critical area	0	0	0	
Any part of the device swallowed	0	0	0	
Allergic reaction to devise material	0	0	0	
Pain due to bent needle	0	0	0	
Any breakage of the device	0	0	0	
Swallowing of material debris observed	0	0	0	
Any other problem	0	5.1	0	
Less than full dose administered	0	1.7	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline in Self-Injection Assessment Questionnaire (SIAQ) domain scores at Week 12

End point title	Absolute change from baseline in Self-Injection Assessment Questionnaire (SIAQ) domain scores at Week 12

End point description:

The three domains of the POST SIAQ are feelings about injections, self-image, self-confidence, injection-site reactions, ease of use, and satisfaction with self-injection. The SIAQ items are scored on a semantic

Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	61	
Units: Score				
arithmetic mean (standard deviation)				
Feelings about injections (n=54, 59, 58)	0.94 (± 2.190)	1.13 (± 1.796)	0.93 (± 1.887)	
Self confidence (n=54, 60, 59)	1.76 (± 1.763)	1.68 (± 1.901)	1.00 (± 2.098)	
Satisfaction with self-injection (n=53, 58, 57)	2.74 (± 2.741)	2.63 (± 2.361)	1.71 (± 2.679)	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline in Self-Injection Assessment Questionnaire (SIAQ) domain scores at Week 48

End point title	Absolute change from baseline in Self-Injection Assessment Questionnaire (SIAQ) domain scores at Week 48

End point description:

The three domains of the POST SIAQ are feelings about injections, self-image, self-confidence, injection-site reactions, ease of use, and satisfaction with self-injection. The SIAQ items are scored on a semantic Likert-type scale where lower numbers indicate a worse experience. Domain scores range from 0 to 10. Subjects self-injecting at this visit completed this SIAQ questionnaire. The POST-SIAQ is taken after the injection at that visit.

End point type	Secondary

End point timeframe:

Absolute change from baseline at week 48

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	Placebo - AIN457 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	60	3	28
Units: Score				
arithmetic mean (standard deviation)				
Feelings about injections	0.92 (± 1.853)	1.34 (± 2.336)	0.42 (± 1.768)	1.43 (± 2.049)
Self confidence	1.88 (± 1.926)	1.86 (± 2.052)	0.00 (± 3.536)	1.17 (± 3.033)
Satisfaction with self-injection	2.93 (± 2.853)	2.50 (± 2.121)	2.50 (± 0.000)	2.29 (± 2.650)

End point values	Placebo - AIN457 300 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	28			
Units: Score				
arithmetic mean (standard deviation)				
Feelings about injections	0.73 (± 1.450)			
Self confidence	1.70 (± 2.145)			
Satisfaction with self-injection	1.98 (± 2.853)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of participants with PASI 50, PASI 75, PASI 90, PASI 100 and IGA 0 or 1 response - induction period

End point title	Percentages of participants with PASI 50, PASI 75, PASI 90, PASI 100 and IGA 0 or 1 response - induction period

End point description:

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 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. 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.

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	61	
Units: Percentages of participants				
number (not applicable)				
PASI 50	78.3	96.7	8.2	
PASI 90	40.0	55.0	0.0	
PASI 100	16.7	26.7	0.0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of participants with PASI 50, PASI 75, PASI 90, PASI 100 and IGA 0 or 1 response - maintenance period (observed data)

End point title	Percentages of participants with PASI 50, PASI 75, PASI 90, PASI 100 and IGA 0 or 1 response - maintenance period (observed data)[1]

End point description:

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 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. 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.

End point type	Secondary

End point timeframe:

Week 12 up to Week 52

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: Descriptive statistics were reported for this endpoint.

End point values	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300 mg
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	61	60	28	28
Units: Percentages of participants				
number (not applicable)				
Week 52 IGA 0/1	64.7	70.7	56.0	85.7
Week 52 PASI 75	82.4	82.8	76.0	96.4
Week 52 PASI 50	96.1	94.8	88.0	100.0
Week 52 PASI 90	62.7	65.5	52.0	89.3
Week 52 PASI 100	35.3	39.7	40.0	64.3

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for PASI score - induction period

End point title	Absolute change from baseline for PASI score - induction period

End point description:

PASI: 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:01, arms:0.2 body:0.3 legs:0.4)

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	61	
Units: Units on a scale				
arithmetic mean (standard deviation)	-15.52 (± 7.841)	-16.67 (± 6.552)	-1.26 (± 6.621)	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for PASI score over time up to week 52 - Maintenance period (observed data)

End point title	Absolute change from baseline for PASI score over time up to week 52 - Maintenance period (observed data)[2]

End point description:

PASI: 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:01, arms:0.2 body:0.3 legs:0.4).

End point type	Secondary

End point timeframe:

Week 52

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: Descriptive statistics were reported for this endpoint.

End point values	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	60	28	28
Units: Units on a scale				
arithmetic mean (standard deviation)	-18.3 (± 6.75)	-16.4 (± 5.99)	-15.2 (± 5.85)	-18.8 (± 5.59)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants in each IGA mod 2011 category - induction period

End point title	Percentage of participants in each IGA mod 2011 category - induction period

End point description:

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

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	61	
Units: Percentages of participants				
number (not applicable)				
clear (n=60, 60, 61)	18.3	30.0	0.0	
almost clear (n=60, 60, 61)	35.0	45.0	0.0	
mild (n=60, 60, 61)	25.0	18.3	8.2	
moderate (n=60, 60, 61)	15.0	6.7	60.7	
severe (n=60, 60, 61)	6.7	0.0	31.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of participants in each IGA mod 2011 category over time up to week 52 - maintenance period (observed data)

End point title	Percentages of participants in each IGA mod 2011 category over time up to week 52 - maintenance period (observed data)[3]

End point description:

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.

End point type	Secondary

End point timeframe:

Week 52

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: Descriptive statistics were reported for this endpoint.

End point values	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	60	28	28
Units: Percentages of participants				
number (not applicable)				
Clear	35.3	39.7	40.0	64.3
Almost clear	29.4	31.0	16.0	21.4

Mild	19.6	19.0	24.0	10.7
Moderate	11.8	6.9	20.0	3.6
Severe	3.9	3.4	0.0	0.0

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in EQ-5D up to week 12 - induction period

End point title	Change from baseline in EQ-5D up to week 12 - induction period

End point description:

ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example "confined to bed") A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state).

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	61	60	61	
Units: unit on a scale				
arithmetic mean (standard deviation)	13.5 (± 19.63)	15.3 (± 19.80)	-0.5 (± 14.89)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in EQ-5D over time up to week 52 - maintenance period

End point title	Change from baseline in EQ-5D over time up to week 52 - maintenance period

End point description:

ED-5Q: Participant rated questionnaire to assess health related quality of life in terms of a single utility score. Five domains are assessed mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) each with three possible score: 1 indicates no problems, better state of health; 3 indicates worst state of health (example "confined to bed") A visual analog scale (VAS) assesses the health status from 0 (worst possible health state) to 100 (best possible health state).

End point type	Secondary

End point timeframe:

Week 52

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	Placebo - AIN457 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	60	3	28
Units: unit on a scale				
arithmetic mean (standard deviation)	16.8 (± 20.34)	17.4 (± 20.38)	10.0 (± 9.00)	12.9 (± 28.45)

End point values	Placebo - AIN457 300mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: unit on a scale				
arithmetic mean (standard deviation)	9.9 (± 10.94)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) score - induction period

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) score - induction period

End point description:

The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions

End point type	Secondary

End point timeframe:

up to Week 12

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	56	55	55	
Units: Units on a scale				
median (confidence interval 95%)	-83.3 (-88.9 to -75.0)	-86.8 (-95.0 to -82.5)	-17.9 (-32.7 to -1.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI) score over time up to Week 52 - maintenance period

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI) score over time up to Week 52 - maintenance period

End point description:

The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions.

End point type	Secondary

End point timeframe:

Week 52

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	Placebo - AIN457 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	55	3	25
Units: Units on a scale				
median (confidence interval 95%)	-90.9 (-95.0 to -85.0)	-91.2 (-94.7 to -84.2)	-53.7 (-72.7 to 9999)	-78.5 (-90.0 to -59.5)

End point values	Placebo - AIN457 300mg			
Subject group type	Reporting group			
Number of subjects analysed	27			
Units: Units on a scale				
median (confidence interval 95%)	-97.7 (-100 to -81.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants achieving a DLQI score of 0 or 1 at week 12 -

induction period

End point title	Percentage of participants achieving a DLQI score of 0 or 1 at week 12 - induction period

End point description:

The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions.

End point type	Secondary

End point timeframe:

Week 12

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	59	59	59	
Units: Percentage of participants				
number (not applicable)	59.3	74.6	15.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of participants achieving a DLQI score of 0 or 1 over time up to week 52 - (maintenance)

End point title	Percentages of participants achieving a DLQI score of 0 or 1 over time up to week 52 - (maintenance)

End point description:

The DLQI is a quality of life measure used in the psoriatic The 10-item questionnaire has a score range of 0 (best) to 30 (worst) with higher scores indicating poor quality of life. The instrument contains six functional scales (i.e., symptoms and feeling, daily activities, leisure, work and school, personal relationships, treatment). Each item has 4 response categories, ranging from 0 (not at all) to 3 (very much). "Not relevant" is also a valid response and is scored as 0. The DLQI total score is a sum of the 10 questions.

End point type	Secondary

End point timeframe:

Week 52

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	Placebo - AIN457 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	60	3	28
Units: Percentage of participants				
number (not applicable)	66.1	70.0	0.0	57.1

End point values	Placebo - AIN457 300mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Percentage of participants				
number (not applicable)	85.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of participants with PASI 50, PASI 75, PASI 90, PASI 100 and IGA 0 or 1 response after week 52 (observed data)

End point title	Percentages of participants with PASI 50, PASI 75, PASI 90, PASI 100 and IGA 0 or 1 response after week 52 (observed data)[4]

End point description:

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 50, 75, 90 and 100 were defined as participants achieving ≥ 50%, 75%, 90% or 100% improvement from baseline. 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.

End point type	Secondary

End point timeframe:

Week 160

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: Descriptive statistics were reported for this endpoint.

End point values	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	60	28	28
Units: Percentages of participants				
number (not applicable)				
IGA 0/1 (n=16, 24, 10, 15) Week 160	43.8	58.3	20.0	73.3
PASI 75 (n=16, 24, 10, 15) Week 160	93.8	87.5	70.0	86.7
PASI 50 (n=16, 24, 10, 15) Week 160	100.0	100.0	70.0	100.0
PASI 90 (n=16, 24, 10, 15) Week 160	62.5	70.8	40.0	73.3
PASI 100 (n=16, 24, 10, 15) Week 160	31.3	45.8	20.0	60.0

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute change from baseline for PASI score after week 52 (observed data)

End point title	Absolute change from baseline for PASI score after week 52 (observed data)[5]

End point description:

PASI: 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:01, arms:0.2 body:0.3 legs:0.4).

End point type	Secondary

End point timeframe:

Week 160

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Descriptive statistics were reported for this endpoint.

End point values	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	60	28	28
Units: Units on a scale				
arithmetic mean (standard deviation)	-18.7 (± 5.66)	-15.9 (± 4.58)	-12.7 (± 8.08)	-18.1 (± 5.49)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of participants in each IGA Mod 2011 category after Week 52 (observed data)

End point title	Percentages of participants in each IGA Mod 2011 category after Week 52 (observed data)[6]

End point description:

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.

End point type	Secondary

End point timeframe:

Week 160

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: Descriptive statistics were reported for this endpoint.

End point values	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	60	28	28
Units: Percentages of participants				
number (not applicable)				
clear (n= 16, 24, 20, 10, 15) Week 160	25.0	45.8	20.0	60.0
almost clear (n= 16, 24, 20, 10, 15) Week 160	18.8	12.5	0.0	13.3
mild (n= 16, 24, 20, 10, 15) Week 160	31.3	20.8	50.0	6.7
moderate (n= 16, 24, 20, 10, 15) Week 160	25.0	16.7	20.0	13.3
severe (n= 16, 24, 20, 10, 15) Week 160	0.0	4.2	10.0	6.7

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants developing treatment-emergent anti-secukinumab antibodies

End point title	Number of participants developing treatment-emergent anti-secukinumab antibodies

End point description:

The development of anti-secunimubab anti-bodies decreases a participant’s ability to respond to secukinumab treatment. The number of participants developing anti-secukinumab anti-bodies was measured from Baseline to week 216.

End point type	Secondary

End point timeframe:

Baseline and at Week 12, 24, 52, 100, 148, 196, 208, and 216

End point values	AIN457 150 mg	AIN457 300 mg	Placebo	Placebo - AIN457 150 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	60	3	28
Units: Number of participants	1	2	0	0

End point values	Placebo - AIN457 300mg			
Subject group type	Reporting group			
Number of subjects analysed	28			
Units: Number of participants	0			

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	Induction AIN457 150 mg
Reporting group description:	
Induction AIN457 150 mg	
Reporting group title	Induction AIN457 300 mg
Reporting group description:	
Induction AIN457 300 mg	
Reporting group title	Induction Placebo
Reporting group description:	
Induction Placebo	
Reporting group title	Entire Any AIN457 150 mg
Reporting group description:	
Entire Any AIN457 150 mg	
Reporting group title	Entire Any AIN457 300 mg
Reporting group description:	
Entire Any AIN457 300 mg	
Reporting group title	Entire Placebo
Reporting group description:	
Entire Placebo	

Serious adverse events	Induction AIN457 150 mg	Induction AIN457 300 mg	Induction Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 61 (4.92%)	1 / 60 (1.67%)	1 / 61 (1.64%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ANOGENITAL WARTS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL CELL CARCINOMA			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BOWEN'S DISEASE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA IN SITU			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
PERIPHERAL ARTERY ANEURYSM			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 ARTERY THROMBOSIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
UTERINE PROLAPSE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
PLEURAL EFFUSION			

subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
MAJOR DEPRESSION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
HEART RATE IRREGULAR			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
BONE CONTUSION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISLOCATION OF VERTEBRA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT FRACTURE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HUMERUS FRACTURE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ULNA FRACTURE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
ANGINA PECTORIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGINA UNSTABLE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AORTIC VALVE STENOSIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK COMPLETE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POSTINFARCTION ANGINA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 TACHYCARDIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
CAROTID ARTERY ANEURYSM			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROPATHY PERIPHERAL			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
AMAUROSIS FUGAX			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CATARACT			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
ASCITES			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS ULCERATIVE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 PROLAPSE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			

CHOLELITHIASIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ACANTHOLYTIC DERMATOSIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLADDER PROLAPSE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUMBAR SPINAL STENOSIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOLYSIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
CHRONIC TONSILLITIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
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			

FLUID OVERLOAD			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (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

Serious adverse events	Entire Any AIN457 150 mg	Entire Any AIN457 300 mg	Entire Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 89 (20.22%)	16 / 88 (18.18%)	1 / 61 (1.64%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
ANOGENITAL WARTS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BOWEN'S DISEASE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (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
LUNG CANCER METASTATIC			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MALIGNANT MELANOMA IN SITU			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
PERIPHERAL ARTERY ANEURYSM			

subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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 ARTERY THROMBOSIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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			
UTERINE PROLAPSE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
PLEURAL EFFUSION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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			
MAJOR DEPRESSION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 88 (0.00%)	1 / 61 (1.64%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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			
HEART RATE IRREGULAR			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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			
BONE CONTUSION			

subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DISLOCATION OF VERTEBRA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
POST PROCEDURAL HAEMORRHAGE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ULNA FRACTURE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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
ANGINA UNSTABLE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (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
AORTIC VALVE STENOSIS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK COMPLETE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC FAILURE			
subjects affected / exposed	1 / 89 (1.12%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CORONARY ARTERY DISEASE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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
LEFT VENTRICULAR DYSFUNCTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PALPITATIONS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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
POSTINFARCTION ANGINA			

subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SINUS TACHYCARDIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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			
CAROTID ARTERY ANEURYSM			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBROVASCULAR ACCIDENT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUROPATHY PERIPHERAL			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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			
AMAUROSIS FUGAX			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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
CATARACT			
subjects affected / exposed	1 / 89 (1.12%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ASCITES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COLITIS ULCERATIVE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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
GASTRITIS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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
INGUINAL HERNIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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 PROLAPSE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
PSORIASIS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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
TRANSIENT ACANTHOLYTIC DERMATOSIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
ACUTE KIDNEY INJURY			

subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (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
BLADDER PROLAPSE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
INTERVERTEBRAL DISC PROTRUSION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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 SPINAL STENOSIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (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
OSTEOARTHRITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OSTEOLYSIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ROTATOR CUFF SYNDROME			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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			
CHRONIC TONSILLITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
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	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (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
MYELITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (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
PNEUMONIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 88 (0.00%)	0 / 61 (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			
FLUID OVERLOAD			
subjects affected / exposed	0 / 89 (0.00%)	1 / 88 (1.14%)	0 / 61 (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

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

Non-serious adverse events	Induction AIN457 150 mg	Induction AIN457 300 mg	Induction Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 61 (57.38%)	37 / 60 (61.67%)	30 / 61 (49.18%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
MELANOCYTIC NAEVUS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

SKIN PAPILLOMA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
HYPERTENSION			
subjects affected / exposed	3 / 61 (4.92%)	1 / 60 (1.67%)	4 / 61 (6.56%)
occurrences (all)	3	1	4
General disorders and administration site conditions			
CYST			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
FATIGUE			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
INJECTION SITE BRUISING			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
INJECTION SITE HAEMATOMA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	2 / 61 (3.28%)
occurrences (all)	0	0	2
INJECTION SITE PAIN			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
PYREXIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Reproductive system and breast disorders			
DYSMENORRHOEA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
COUGH			
subjects affected / exposed	0 / 61 (0.00%)	3 / 60 (5.00%)	2 / 61 (3.28%)
occurrences (all)	0	3	2
DYSPHONIA			
subjects affected / exposed	0 / 61 (0.00%)	2 / 60 (3.33%)	0 / 61 (0.00%)
occurrences (all)	0	4	0
DYSPNOEA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
EPISTAXIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	1 / 61 (1.64%)
occurrences (all)	0	1	1
OROPHARYNGEAL PAIN			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	2 / 61 (3.28%)
occurrences (all)	0	1	2
RHINORRHOEA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
ADJUSTMENT DISORDER WITH DEPRESSED MOOD			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
DEPRESSION			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
INSOMNIA			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
BLOOD URINE PRESENT			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
WEIGHT DECREASED			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
WEIGHT INCREASED			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
ANIMAL BITE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

ARTHROPOD STING			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
CONTUSION			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
FALL			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
JOINT DISLOCATION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
LACERATION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
MUSCLE STRAIN			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	6	0
PROCEDURAL PAIN			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
SUNBURN			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
TENDON RUPTURE			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
TOOTH FRACTURE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
ANGINA PECTORIS			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
AORTIC VALVE INCOMPETENCE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
SINUS BRADYCARDIA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	5 / 61 (8.20%)	3 / 60 (5.00%)	3 / 61 (4.92%)
occurrences (all)	5	3	6
HYPOAESTHESIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
PARAESTHESIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
SCIATICA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
EOSINOPHILIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
LYMPHADENOPATHY			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
Eye disorders			

BLEPHARITIS			
subjects affected / exposed	0 / 61 (0.00%)	2 / 60 (3.33%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
CONSTIPATION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
DENTAL CARIES			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
DIARRHOEA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
DYSPEPSIA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
GASTRITIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
INGUINAL HERNIA			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
NAUSEA			
subjects affected / exposed	0 / 61 (0.00%)	2 / 60 (3.33%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
TOOTHACHE			
subjects affected / exposed	1 / 61 (1.64%)	2 / 60 (3.33%)	2 / 61 (3.28%)
occurrences (all)	1	2	2
VOMITING			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
ACTINIC KERATOSIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
DERMATITIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
DRUG ERUPTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
DRY SKIN			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
ECZEMA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
HYPERKERATOSIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
INTERTRIGO			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
PITYRIASIS ROSEA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
PRURITUS			

subjects affected / exposed	1 / 61 (1.64%)	4 / 60 (6.67%)	2 / 61 (3.28%)
occurrences (all)	1	4	3
PRURITUS GENERALISED			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
PSORIASIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
SEBORRHOEA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	0 / 61 (0.00%)	2 / 60 (3.33%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
STASIS DERMATITIS			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
HAEMATURIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
BACK PAIN			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
BURSITIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
FIBROMYALGIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
INTERVERTEBRAL DISC DEGENERATION			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
MUSCLE SPASMS			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
MYALGIA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
NECK PAIN			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
OSTEOARTHRITIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	2 / 61 (3.28%)
occurrences (all)	0	0	2
PAIN IN EXTREMITY			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	1 / 61 (1.64%)
occurrences (all)	1	2	1
PSORIATIC ARTHROPATHY			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
TENDONITIS			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	1 / 61 (1.64%)
occurrences (all)	0	1	1
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	2 / 61 (3.28%)
occurrences (all)	1	0	2
CANDIDA INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
CONJUNCTIVITIS			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0

CYSTITIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
EAR INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
FOLLICULITIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
FUNGAL INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	2 / 61 (3.28%)
occurrences (all)	1	1	2
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
HORDEOLUM			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	1
INFLUENZA			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	2 / 61 (3.28%)
occurrences (all)	1	0	2
NASOPHARYNGITIS			
subjects affected / exposed	14 / 61 (22.95%)	19 / 60 (31.67%)	9 / 61 (14.75%)
occurrences (all)	15	22	10
ORAL CANDIDIASIS			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	0	0	1
ORAL HERPES			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
OTITIS EXTERNA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
OTITIS MEDIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
PERIODONTITIS			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
PHARYNGITIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
PHARYNGITIS STREPTOCOCCAL			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
PULPITIS DENTAL			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
PYURIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
RHINITIS			
subjects affected / exposed	2 / 61 (3.28%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
SINUSITIS			
subjects affected / exposed	1 / 61 (1.64%)	3 / 60 (5.00%)	0 / 61 (0.00%)
occurrences (all)	2	3	0
TINEA PEDIS			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
TONSILLITIS			

subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
TOOTH ABSCESS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	1 / 61 (1.64%)
occurrences (all)	1	0	2
TOOTH INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	1 / 60 (1.67%)	1 / 61 (1.64%)
occurrences (all)	0	1	1
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	1 / 61 (1.64%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
GOUT			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
HYPERLIPIDAEMIA			
subjects affected / exposed	1 / 61 (1.64%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	1	1	0
HYPERTRIGLYCERIDAEMIA			

subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
VITAMIN B12 DEFICIENCY			
subjects affected / exposed	0 / 61 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Entire Any AIN457 150 mg	Entire Any AIN457 300 mg	Entire Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	81 / 89 (91.01%)	81 / 88 (92.05%)	31 / 61 (50.82%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
MELANOCYTIC NAEVUS			
subjects affected / exposed	3 / 89 (3.37%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	3	0	0
SKIN PAPILLOMA			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	3	0
HYPERTENSION			
subjects affected / exposed	4 / 89 (4.49%)	10 / 88 (11.36%)	4 / 61 (6.56%)
occurrences (all)	4	11	4
General disorders and administration site conditions			
CYST			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
FATIGUE			
subjects affected / exposed	4 / 89 (4.49%)	3 / 88 (3.41%)	1 / 61 (1.64%)
occurrences (all)	5	4	1

INJECTION SITE BRUISING			
subjects affected / exposed	1 / 89 (1.12%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	2	5	0
INJECTION SITE HAEMATOMA			
subjects affected / exposed	1 / 89 (1.12%)	3 / 88 (3.41%)	2 / 61 (3.28%)
occurrences (all)	1	3	2
INJECTION SITE PAIN			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	2	0
NON-CARDIAC CHEST PAIN			
subjects affected / exposed	3 / 89 (3.37%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	3	1	0
PYREXIA			
subjects affected / exposed	0 / 89 (0.00%)	5 / 88 (5.68%)	0 / 61 (0.00%)
occurrences (all)	0	12	0
Immune system disorders			
DRUG HYPERSENSITIVITY			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
Reproductive system and breast disorders			
DYSMENORRHOEA			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 89 (0.00%)	5 / 88 (5.68%)	0 / 61 (0.00%)
occurrences (all)	0	6	0
COUGH			
subjects affected / exposed	5 / 89 (5.62%)	10 / 88 (11.36%)	2 / 61 (3.28%)
occurrences (all)	5	13	2
DYSPHONIA			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	5	0
DYSPNOEA			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0

EPISTAXIS			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
NASAL CONGESTION			
subjects affected / exposed	0 / 89 (0.00%)	4 / 88 (4.55%)	1 / 61 (1.64%)
occurrences (all)	0	4	1
OROPHARYNGEAL PAIN			
subjects affected / exposed	4 / 89 (4.49%)	8 / 88 (9.09%)	2 / 61 (3.28%)
occurrences (all)	4	10	2
RHINORRHOEA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
ADJUSTMENT DISORDER WITH DEPRESSED MOOD			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
DEPRESSION			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
INSOMNIA			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	2	0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	3 / 89 (3.37%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	3	2	0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 89 (2.25%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	2	2	0
BLOOD URINE PRESENT			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	3	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			

subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
LIVER FUNCTION TEST INCREASED			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
WEIGHT DECREASED			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	1 / 61 (1.64%)
occurrences (all)	2	0	1
WEIGHT INCREASED			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
Injury, poisoning and procedural complications			
ANIMAL BITE			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
ARTHROPOD BITE			
subjects affected / exposed	2 / 89 (2.25%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	2	4	0
ARTHROPOD STING			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
CONTUSION			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	3	1	0
FALL			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	2	2	0
JOINT DISLOCATION			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
LACERATION			
subjects affected / exposed	2 / 89 (2.25%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	2	4	0
MUSCLE STRAIN			

subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	3	0
POST PROCEDURAL COMPLICATION			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	30	0
PROCEDURAL PAIN			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
SUNBURN			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	3	0
TENDON RUPTURE			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
TOOTH FRACTURE			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	1 / 89 (1.12%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	1	3	0
AORTIC VALVE INCOMPETENCE			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE			
subjects affected / exposed	0 / 89 (0.00%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	0	5	0
BUNDLE BRANCH BLOCK LEFT			
subjects affected / exposed	1 / 89 (1.12%)	3 / 88 (3.41%)	1 / 61 (1.64%)
occurrences (all)	1	3	1
SINUS BRADYCARDIA			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			

HEADACHE			
subjects affected / exposed	13 / 89 (14.61%)	14 / 88 (15.91%)	3 / 61 (4.92%)
occurrences (all)	16	28	6
HYPOAESTHESIA			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
PARAESTHESIA			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
SCIATICA			
subjects affected / exposed	3 / 89 (3.37%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	3	0	0
Blood and lymphatic system disorders			
EOSINOPHILIA			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	2	0
LYMPHADENOPATHY			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	2	0
Eye disorders			
BLEPHARITIS			
subjects affected / exposed	0 / 89 (0.00%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	0	6	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	1 / 61 (1.64%)
occurrences (all)	2	1	1
ABDOMINAL PAIN UPPER			
subjects affected / exposed	3 / 89 (3.37%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	3	1	0
CONSTIPATION			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
DENTAL CARIES			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	1 / 61 (1.64%)
occurrences (all)	2	0	1
DIARRHOEA			

subjects affected / exposed	6 / 89 (6.74%)	7 / 88 (7.95%)	0 / 61 (0.00%)
occurrences (all)	8	9	0
DYSPEPSIA			
subjects affected / exposed	3 / 89 (3.37%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	4	1	0
GASTRITIS			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	4	1	0
INGUINAL HERNIA			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
NAUSEA			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	5	0
TOOTHACHE			
subjects affected / exposed	5 / 89 (5.62%)	5 / 88 (5.68%)	2 / 61 (3.28%)
occurrences (all)	8	5	2
VOMITING			
subjects affected / exposed	2 / 89 (2.25%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	2	3	0
Hepatobiliary disorders			
HEPATIC STEATOSIS			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
ACTINIC KERATOSIS			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
DERMATITIS			
subjects affected / exposed	3 / 89 (3.37%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	3	0	0
DRUG ERUPTION			
subjects affected / exposed	3 / 89 (3.37%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	3	0	0
DRY SKIN			

subjects affected / exposed	0 / 89 (0.00%)	5 / 88 (5.68%)	0 / 61 (0.00%)
occurrences (all)	0	5	0
ECZEMA			
subjects affected / exposed	5 / 89 (5.62%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	7	2	0
HYPERKERATOSIS			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	3	0
INTERTRIGO			
subjects affected / exposed	3 / 89 (3.37%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	4	0	0
PAIN OF SKIN			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	1 / 61 (1.64%)
occurrences (all)	0	2	1
PITYRIASIS ROSEA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
PRURITUS			
subjects affected / exposed	3 / 89 (3.37%)	7 / 88 (7.95%)	2 / 61 (3.28%)
occurrences (all)	3	8	3
PRURITUS GENERALISED			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	5	0
PSORIASIS			
subjects affected / exposed	6 / 89 (6.74%)	7 / 88 (7.95%)	1 / 61 (1.64%)
occurrences (all)	7	7	1
SEBORRHOEA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	6	0
SEBORRHOEIC DERMATITIS			
subjects affected / exposed	3 / 89 (3.37%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	3	6	0
STASIS DERMATITIS			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	2	0
Renal and urinary disorders			

HAEMATURIA			
subjects affected / exposed	3 / 89 (3.37%)	6 / 88 (6.82%)	0 / 61 (0.00%)
occurrences (all)	3	6	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	11 / 89 (12.36%)	9 / 88 (10.23%)	0 / 61 (0.00%)
occurrences (all)	11	12	0
BACK PAIN			
subjects affected / exposed	5 / 89 (5.62%)	9 / 88 (10.23%)	0 / 61 (0.00%)
occurrences (all)	6	10	0
BURSITIS			
subjects affected / exposed	1 / 89 (1.12%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	1	3	0
FIBROMYALGIA			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
INTERVERTEBRAL DISC DEGENERATION			
subjects affected / exposed	2 / 89 (2.25%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	2	0	0
MUSCLE SPASMS			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	3	0
MUSCULOSKELETAL PAIN			
subjects affected / exposed	3 / 89 (3.37%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	3	4	0
MYALGIA			
subjects affected / exposed	2 / 89 (2.25%)	3 / 88 (3.41%)	1 / 61 (1.64%)
occurrences (all)	2	3	1
NECK PAIN			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
OSTEOARTHRITIS			
subjects affected / exposed	1 / 89 (1.12%)	3 / 88 (3.41%)	2 / 61 (3.28%)
occurrences (all)	1	3	2
PAIN IN EXTREMITY			

subjects affected / exposed	2 / 89 (2.25%)	3 / 88 (3.41%)	1 / 61 (1.64%)
occurrences (all)	2	5	1
PSORIATIC ARTHROPATHY			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	3	0
TENDONITIS			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	1 / 61 (1.64%)
occurrences (all)	0	2	1
Infections and infestations			
BRONCHITIS			
subjects affected / exposed	6 / 89 (6.74%)	11 / 88 (12.50%)	2 / 61 (3.28%)
occurrences (all)	8	14	2
CANDIDA INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
CONJUNCTIVITIS			
subjects affected / exposed	4 / 89 (4.49%)	6 / 88 (6.82%)	0 / 61 (0.00%)
occurrences (all)	4	6	0
CYSTITIS			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
EAR INFECTION			
subjects affected / exposed	1 / 89 (1.12%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	2	3	0
FOLLICULITIS			
subjects affected / exposed	4 / 89 (4.49%)	0 / 88 (0.00%)	1 / 61 (1.64%)
occurrences (all)	4	0	1
FUNGAL INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	0	4	0
FUNGAL SKIN INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
GASTROENTERITIS			
subjects affected / exposed	6 / 89 (6.74%)	7 / 88 (7.95%)	2 / 61 (3.28%)
occurrences (all)	6	8	2

GASTROENTERITIS VIRAL			
subjects affected / exposed	3 / 89 (3.37%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	3	3	0
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
HORDEOLUM			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	1 / 61 (1.64%)
occurrences (all)	1	3	1
INFLUENZA			
subjects affected / exposed	8 / 89 (8.99%)	0 / 88 (0.00%)	2 / 61 (3.28%)
occurrences (all)	10	0	2
NASOPHARYNGITIS			
subjects affected / exposed	37 / 89 (41.57%)	39 / 88 (44.32%)	9 / 61 (14.75%)
occurrences (all)	66	96	10
ORAL CANDIDIASIS			
subjects affected / exposed	0 / 89 (0.00%)	4 / 88 (4.55%)	1 / 61 (1.64%)
occurrences (all)	0	5	1
ORAL HERPES			
subjects affected / exposed	4 / 89 (4.49%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	4	7	0
OTITIS EXTERNA			
subjects affected / exposed	1 / 89 (1.12%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	2	4	0
OTITIS MEDIA			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	2	1	0
PERIODONTITIS			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	2	0
PHARYNGITIS			
subjects affected / exposed	5 / 89 (5.62%)	5 / 88 (5.68%)	0 / 61 (0.00%)
occurrences (all)	6	5	0
PHARYNGITIS STREPTOCOCCAL			

subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
PULPITIS DENTAL			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	2	0
PYURIA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
RHINITIS			
subjects affected / exposed	6 / 89 (6.74%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	6	1	0
SINUSITIS			
subjects affected / exposed	5 / 89 (5.62%)	7 / 88 (7.95%)	0 / 61 (0.00%)
occurrences (all)	6	11	0
TINEA PEDIS			
subjects affected / exposed	1 / 89 (1.12%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	1	2	0
TONSILLITIS			
subjects affected / exposed	2 / 89 (2.25%)	4 / 88 (4.55%)	0 / 61 (0.00%)
occurrences (all)	6	4	0
TOOTH ABSCESS			
subjects affected / exposed	2 / 89 (2.25%)	1 / 88 (1.14%)	1 / 61 (1.64%)
occurrences (all)	2	2	2
TOOTH INFECTION			
subjects affected / exposed	3 / 89 (3.37%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	3	3	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	17 / 89 (19.10%)	9 / 88 (10.23%)	1 / 61 (1.64%)
occurrences (all)	27	13	1
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 89 (2.25%)	3 / 88 (3.41%)	0 / 61 (0.00%)
occurrences (all)	2	3	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	3 / 89 (3.37%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	3	3	0
VULVOVAGINAL CANDIDIASIS			
subjects affected / exposed	4 / 89 (4.49%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	4	1	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	3 / 89 (3.37%)	0 / 88 (0.00%)	0 / 61 (0.00%)
occurrences (all)	4	0	0
Metabolism and nutrition disorders			
GOUT			
subjects affected / exposed	2 / 89 (2.25%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	2	2	0
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	3 / 89 (3.37%)	1 / 88 (1.14%)	0 / 61 (0.00%)
occurrences (all)	3	1	0
HYPERLIPIDAEMIA			
subjects affected / exposed	2 / 89 (2.25%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	2	2	0
HYPERTRIGLYCERIDAEMIA			
subjects affected / exposed	2 / 89 (2.25%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	3	2	0
HYPERURICAEMIA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0
VITAMIN B12 DEFICIENCY			
subjects affected / exposed	0 / 89 (0.00%)	2 / 88 (2.27%)	0 / 61 (0.00%)
occurrences (all)	0	2	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 August 2013	Added an open-label Extension period with continued treatment for another 156 weeks or until the drug is available in the country of participation for eligible patients, who were on active therapy during the Maintenance period. Specified the rescreening procedures. Specified that at Week 52 the sites become aware which patients received placebo during the Maintenance period. After the Week 52 data base lock, the study will be open- label. Introduced home administration of study treatment for certain visits in the Extension period. Clarified concomitant medications and specified that topical corticosteroid use is allowed under certain restrictions, during the Extension period. Added instructions to report defects, malfunctions or product complaints for the AI and introduced Use of Device (AI) eCRF for the extension treatment period to record such information.

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.

Efficacy results after Wk 160 can't be interpreted meaningfully due to low # of evaluable patients. As per protocol, availability of AIN457 in participating countries led to discontinuation of most patients before they reached the later visits.

Notes: