



Clinical trial results:

Study of the Safety and Efficacy of LY3016859 after Multiple Intravenous Dosing in Diabetic Nephropathy Patients

Summary

EudraCT number	2012-004496-40
Trial protocol	BG GB
Global end of trial date	13 August 2015

Results information

Result version number	v1 (current)
This version publication date	06 September 2017
First version publication date	06 September 2017

Trial information

Trial identification

Sponsor protocol code	ISV-MC-TGAB
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01774981
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 14353

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 8772854559,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 August 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this two-part study is to investigate the safety, tolerability and efficacy of LY3016859 after multiple intravenous (IV) dosing in participants with diabetic nephropathy (DN). Part A will be dose escalation for safety and tolerability and Part B will evaluate Proteinuria.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	22 March 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 37
Country: Number of subjects enrolled	Bulgaria: 18
Country: Number of subjects enrolled	United Kingdom: 5
Worldwide total number of subjects	60
EEA total number of subjects	23

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)	43
From 65 to 84 years	17

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

No Text Entered

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
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Arm title	Placebo (Part A)
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Arm description:

Part A: Placebo administered by 60 minute Intravenous (IV) infusion at Week 1 and Week 4.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Administered by 60 minute Intravenous (IV) infusion at Week 1 and Week 4.

Arm title	10 mg LY3016859 (Part A)
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Arm description:

Part A: 10 milligram (mg) LY3016859 administered by 60 minute IV infusion at Week 1 and Week 4.

Arm type	Experimental
Investigational medicinal product name	LY3016859
Investigational medicinal product code	
Other name	TGFa/Epiregulin Antibody
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

10 milligram (mg) administered by 60 minute Intravenous (IV) infusion at Week 1 and Week 4.

Arm title	100 mg LY3016859 (Part A)
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Arm description:

Part A: 100 mg LY3016859 administered by 60 minute IV infusion at Week 1 and Week 4.

Arm type	Experimental
Investigational medicinal product name	LY3016859
Investigational medicinal product code	
Other name	TGFa/Epiregulin Antibody
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

100 mg administered by 60 minute Intravenous (IV) infusion at Week 1 and Week 4.

Arm title	750 mg LY3016859 (Part A)
Arm description: Part A: 750 mg LY3016859 administered by 60 minute IV infusion at Week 1 and Week 4.	
Arm type	Experimental
Investigational medicinal product name	LY3016859
Investigational medicinal product code	
Other name	TGFa/Epiregulin Antibody
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: 750 mg administered by 60 minute Intravenous (IV) infusion at Week 1 and Week 4.	
Arm title	Placebo (Part B)
Arm description: Part B: Placebo administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	
Arm type	Placebo
Investigational medicinal product name	Placebo (Part B)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: Administered by 60 minute Intravenous (IV) infusion at Weeks 1, 4, 7, 10 and 13.	
Arm title	50 mg LY3016859 (Part B)
Arm description: Part B: 50 mg LY3016859 administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	
Arm type	Experimental
Investigational medicinal product name	LY3016859
Investigational medicinal product code	
Other name	TGFa/Epiregulin Antibody
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: 50 mg administered by 60 minute Intravenous (IV) infusion at Weeks 1, 4, 7, 10 and 13.	
Arm title	250 mg LY3016859 (Part B)
Arm description: Part B: 250 mg LY3016859 administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	
Arm type	Experimental
Investigational medicinal product name	LY3016859
Investigational medicinal product code	
Other name	TGFa/Epiregulin Antibody
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: 250 mg administered by 60 minute Intravenous (IV) infusion at Weeks 1, 4, 7, 10 and 13.	
Arm title	750 mg LY3016859 (Part B)
Arm description: Part B: 750 mg LY3016859 administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	
Arm type	Experimental

Investigational medicinal product name	LY3016859
Investigational medicinal product code	
Other name	TGFa/Epiregulin Antibody
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

750 mg administered by 60 minute Intravenous (IV) infusion at Weeks 1, 4, 7, 10 and 13.

Number of subjects in period 1	Placebo (Part A)	10 mg LY3016859 (Part A)	100 mg LY3016859 (Part A)
Started	3	4	4
Received at least 1 dose of study drug	3	4	4
Completed	3	4	4
Not completed	0	0	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-

Number of subjects in period 1	750 mg LY3016859 (Part A)	Placebo (Part B)	50 mg LY3016859 (Part B)
Started	4	6	14
Received at least 1 dose of study drug	4	6	14
Completed	4	5	13
Not completed	0	1	1
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	1

Number of subjects in period 1	250 mg LY3016859 (Part B)	750 mg LY3016859 (Part B)
Started	13	12
Received at least 1 dose of study drug	13	12
Completed	13	11
Not completed	0	1
Adverse event, serious fatal	-	-
Consent withdrawn by subject	-	1
Adverse event, non-fatal	-	-

Baseline characteristics

Reporting groups

Reporting group title	Overall Study
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Reporting group description:

Baseline Analysis Population Description : All randomized participants who received at least one dose of study drug.

Reporting group values	Overall Study	Total	
Number of subjects	60	60	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	43	43	
From 65-84 years	17	17	
85 years and over	0	0	
Age Continuous			
Units: years			
arithmetic mean	58.5		
standard deviation	± 9.6	-	
Gender, Male/Female			
Units:			
Male	32	32	
Female	28	28	
Region of Enrollment			
Units: Subjects			
United States	37	37	
Bulgaria	18	18	
United Kingdom	5	5	
Ethnicity			
Units: Subjects			
Hispanic or Latino	10	10	
Not Hispanic or Latino	50	50	
Unknown or Not Reported	0	0	
Race			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	2	2	
White	58	58	
More than one race	0	0	

Unknown or Not Reported	0	0	
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End points

End points reporting groups

Reporting group title	Placebo (Part A)
Reporting group description: Part A: Placebo administered by 60 minute Intravenous (IV) infusion at Week 1 and Week 4.	
Reporting group title	10 mg LY3016859 (Part A)
Reporting group description: Part A: 10 milligram (mg) LY3016859 administered by 60 minute IV infusion at Week 1 and Week 4.	
Reporting group title	100 mg LY3016859 (Part A)
Reporting group description: Part A: 100 mg LY3016859 administered by 60 minute IV infusion at Week 1 and Week 4.	
Reporting group title	750 mg LY3016859 (Part A)
Reporting group description: Part A: 750 mg LY3016859 administered by 60 minute IV infusion at Week 1 and Week 4.	
Reporting group title	Placebo (Part B)
Reporting group description: Part B: Placebo administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	
Reporting group title	50 mg LY3016859 (Part B)
Reporting group description: Part B: 50 mg LY3016859 administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	
Reporting group title	250 mg LY3016859 (Part B)
Reporting group description: Part B: 250 mg LY3016859 administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	
Reporting group title	750 mg LY3016859 (Part B)
Reporting group description: Part B: 750 mg LY3016859 administered by 60 minute IV infusion at Weeks 1, 4, 7, 10 and 13.	

Primary: Part B:Change from Baseline in Proteinuria

End point title	Part B:Change from Baseline in Proteinuria ^[1]
End point description: Proteinuria is defined as the ratio of protein to creatinine.	
Analysis Population Description : All randomized participants who received at least one dose of study drug in Part B with a baseline measurement and at least one post-baseline measurement.	
End point type	Primary
End point timeframe: Baseline, 16 Weeks	
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: Analyses were only planned for Part B.

End point values	Placebo (Part B)	50 mg LY3016859 (Part B)	250 mg LY3016859 (Part B)	750 mg LY3016859 (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	9	9	11
Units: grams per 12 hour (g/12 hour)				
arithmetic mean (standard deviation)	1.5 (± 2.04)	-0.4 (± 1.6)	0.1 (± 1.21)	0.7 (± 2.23)

Statistical analyses

Statistical analysis title	STATISTICAL_ANALYSIS_1_Proteinuria
Comparison groups	50 mg LY3016859 (Part B) v Placebo (Part B)
Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0449
Method	t-test, 1-sided

Statistical analysis title	STATISTICAL_ANALYSIS_2_Proteinuria
Comparison groups	Placebo (Part B) v 250 mg LY3016859 (Part B)
Number of subjects included in analysis	15
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0808
Method	t-test, 1-sided

Statistical analysis title	STATISTICAL_ANALYSIS_3_Proteinuria
Comparison groups	Placebo (Part B) v 750 mg LY3016859 (Part B)
Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2219
Method	t-test, 1-sided

Primary: Part A and Part B: Number of Participants with One or More Treatment Emergent Adverse Events (AEs) or Any Serious AEs

End point title	Part A and Part B: Number of Participants with One or More Treatment Emergent Adverse Events (AEs) or Any Serious AEs ^[2]
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End point description:

Treatment-emergent adverse events (TEAEs) are events which were not present at baseline or pre-existing conditions at baseline that worsened in severity following the start of treatment. A summary of other non-serious Adverse Events (AEs), and all Serious Adverse Events (SAE's), regardless of causality, is located in the Reported Adverse Events section.

Analysis Population Description: All randomized participants who received at least one dose of study drug.

End point type	Primary
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End point timeframe:

Baseline up to 32 Weeks

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No arm comparison analyses were planned or conducted.

End point values	Placebo (Part A)	10 mg LY3016859 (Part A)	100 mg LY3016859 (Part A)	750 mg LY3016859 (Part A)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	4	4
Units: participants				
number (not applicable)	1	3	4	2

End point values	Placebo (Part B)	50 mg LY3016859 (Part B)	250 mg LY3016859 (Part B)	750 mg LY3016859 (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	14	13	12
Units: participants				
number (not applicable)	6	13	13	11

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Proteinuria Over Time

End point title	Part B: Change from Baseline in Proteinuria Over Time ^[3]
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End point description:

Proteinuria is defined as the ratio of protein to creatinine.

Analysis Population Description : All randomized participants who received at least one dose of study drug and were in Part B with a baseline measurement and at least one post-baseline measurement.

End point type	Secondary
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End point timeframe:

Baseline, 19 Weeks

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: Analyses were only planned for Part B.

End point values	Placebo (Part B)	50 mg LY3016859 (Part B)	250 mg LY3016859 (Part B)	750 mg LY3016859 (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	11	12	11
Units: mg/dl of protein/ by mg/dl of creatinine				
arithmetic mean (standard deviation)	19.3 (± 154.66)	-17.3 (± 81.95)	-2.4 (± 88.01)	48.6 (± 130.13)

Statistical analyses

No statistical analyses for this end point

Secondary: Part B: Change from Baseline in Albuminuria Over Time

End point title	Part B: Change from Baseline in Albuminuria Over Time ^[4]
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End point description:

Albuminuria is defined as the ratio of albumin to creatinine.

Analysis Population Description : All randomized participants who received at least one dose of study drug and were in Part B with a baseline measurement and at least one post-baseline measurement.

End point type	Secondary
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End point timeframe:

Baseline, 19 Weeks

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: Analyses were only planned for Part B.

End point values	Placebo (Part B)	50 mg LY3016859 (Part B)	250 mg LY3016859 (Part B)	750 mg LY3016859 (Part B)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	11	12	11
Units: mg/dl of albumin/ by mg/dl of creatinine				
arithmetic mean (standard deviation)	8.6 (± 100.57)	-15.6 (± 64.27)	-8.1 (± 50.19)	36.7 (± 93.49)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

I5V-MC-TGAB

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.0
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Reporting groups

Reporting group title	A-PLACEBO
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Reporting group description: -

Reporting group title	B-PLACEBO
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Reporting group description: -

Reporting group title	A-LY3016859-10mg
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Reporting group description: -

Reporting group title	A-LY3016859-100mg
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Reporting group description: -

Reporting group title	A-LY3016859-750mg
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Reporting group description: -

Reporting group title	B-LY3016859-50mg
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Reporting group description: -

Reporting group title	B-LY3016859-250mg
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Reporting group description: -

Reporting group title	B-LY3016859-750mg
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Reporting group description: -

Serious adverse events	A-PLACEBO	B-PLACEBO	A-LY3016859-10mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
anginal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 aggravated			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 with rapid ventricular response			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive heart failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
femoropopliteal artery bypass			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
lacunar infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 ischemic attack			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
sudden death			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Gastrointestinal disorders			
gastrointestinal bleed			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
phytobezoar			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
acalculous cholecystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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			
dyspnea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
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 lower extremity cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	A-LY3016859-100mg	A-LY3016859-750mg	B-LY3016859-50mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	3 / 14 (21.43%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
anginal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
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 aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
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 with rapid ventricular response			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive heart failure			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
femoropopliteal artery bypass			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
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			
lacunar infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischemic attack			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
sudden death			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
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			
gastrointestinal bleed			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
phytobezoar			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
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			
acalculous cholecystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
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			
dyspnea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
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 lower extremity cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
clostridium difficile colitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Serious adverse events			
	B-LY3016859-250mg	B-LY3016859-750mg	
Total subjects affected by serious			

adverse events			
subjects affected / exposed	6 / 13 (46.15%)	2 / 12 (16.67%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
anginal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
atrial fibrillation with rapid ventricular response			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
congestive heart failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
femoropopliteal artery bypass			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
lacunar infarction			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
transient ischemic attack			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
sudden death			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
gastrointestinal bleed			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
phytobezoar			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
acalculous cholecystitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
dyspnea			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
chronic lower extremity cellulitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
clostridium difficile colitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
peritonitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	A-PLACEBO	B-PLACEBO	A-LY3016859-10mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	6 / 6 (100.00%)	3 / 4 (75.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
thyroid nodule			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
blood pressure high			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
flushing of face			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
hematoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypertension exacerbated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypertension worsened			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
orthostatic hypotension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
mohs micrographic surgery			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
squamous cell carcinoma excision			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
application site pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
chest pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
coldness general			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
edema aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
edema generalized			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fatigue aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fever			
alternative dictionary used: MedDRA 17.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>general body pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>swelling of legs</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>systemic inflammatory response syndrome</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>infusion site erythema</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>1 / 3 (33.33%)</p> <p>1</p>	<p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Immune system disorders</p> <p>hay fever</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 3 (33.33%)</p> <p>1</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Reproductive system and breast disorders</p> <p>nipple pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>allergic rhinitis</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>cough</p> <p>alternative dictionary used: MedDRA 17.0</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cough nonproductive			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dyspnea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
epistaxis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
laryngeal cyst			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
nosebleed			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pleural effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
rhinorrhea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
sore throat			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

supine dyspnea alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
runny nose subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Psychiatric disorders depression worsened alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
difficulty sleeping alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Investigations bicarbonate decreased serum alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
blood creatinine increased alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
blood glucose increased alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 2	0 / 4 (0.00%) 0
blood pressure increased alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
cholesterol levels raised alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ecg abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fasting blood glucose abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
increased intraocular pressure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
platelets decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
potassium abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
potassium increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
renal function test abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
thyroid function test abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

<p>uric acid level increased</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>weight gain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Injury, poisoning and procedural complications</p> <p>abrasions</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ankle sprain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>bruising</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>excoriation</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>first degree burns</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>flea bite</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>hematoma traumatic</p> <p>alternative dictionary used:</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>

MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
lower limb wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
spider bite			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
sprained ankle			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
bradycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
heart pounding			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
tachycardia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 3 (33.33%)	2 / 6 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
headache aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
lightheadedness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
numbness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
presyncope			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
sciatica aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
body numbness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
crawling sensation			

subjects affected / exposed	1 / 3 (33.33%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
numbness in feet			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
anemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
anemia aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
cloudy vision			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
glaucoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
right cataract			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
tearing decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

visual acuity reduced alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Gastrointestinal disorders			
abdominal cramps alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
abdominal fullness alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
colitis alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
diarrhea alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
distress gastrointestinal alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
dry heaves alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
dry mouth alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
heartburn alternative dictionary used: MedDRA 17.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nausea</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>toothache</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>vomiting</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p> <p>1 / 6 (16.67%)</p> <p>1</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>1 / 6 (16.67%)</p> <p>1</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Hepatobiliary disorders</p> <p>portal vein phlebitis</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Skin and subcutaneous tissue disorders</p> <p>acne</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>blister</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>diaphoresis</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>ecchymosis</p> <p>alternative dictionary used: MedDRA 17.0</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
generalized itching			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
itching			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
localised rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
localized erythema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
papular rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
pruritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

<p>skin inflammation</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>skin irritation</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>skin peeling</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>
<p>Renal and urinary disorders</p> <p>acute kidney injury</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>chronic kidney disease</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>diuresis</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>kidney function abnormal</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>urinary retention</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p> <p>0 / 3 (0.00%)</p> <p>0</p>	<p>0 / 6 (0.00%)</p> <p>0</p> <p>2 / 6 (33.33%)</p> <p>2</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p> <p>0 / 6 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p> <p>0 / 4 (0.00%)</p> <p>0</p>
<p>Musculoskeletal and connective tissue disorders</p>			

back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
chest wall pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
flank pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
foot pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
low back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
muscle cramps			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
pain in thumb			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
shoulder pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

alpha hemolytic streptococcal infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
axillary abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
bacterial infection due to unspecified staphylococcus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cellulitis of hand			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cellulitis of leg			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
cold			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
common cold			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
dental abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
flu			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
head cold			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
kidney infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
leg infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

tooth infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
upper respiratory infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
urinary tract infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
urinary tract yeast infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
viral infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
viral labyrinthitis alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
viral syndrome alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
Metabolism and nutrition disorders appetite lost alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 6 (16.67%) 1	0 / 4 (0.00%) 0
dehydration alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
fasting hyperglycemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
gout aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
gout flare			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hyperkalemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypoglycemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 6 (16.67%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
hypoglycemia aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
hypokalemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
metabolic acidosis worsened			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

volume depletion alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0
volume overload alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 6 (0.00%) 0	0 / 4 (0.00%) 0

Non-serious adverse events	A-LY3016859-100mg	A-LY3016859-750mg	B-LY3016859-50mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	2 / 4 (50.00%)	13 / 14 (92.86%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
squamous cell carcinoma alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
thyroid nodule alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
Vascular disorders			
blood pressure high alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
flushing of face alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
hematoma			

<p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 14 (7.14%)</p> <p>1</p>
<p>hypertension exacerbated</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 14 (7.14%)</p> <p>1</p>
<p>hypertension worsened</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>1 / 14 (7.14%)</p> <p>1</p>
<p>orthostatic hypotension</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>2 / 14 (14.29%)</p> <p>2</p>
<p>Surgical and medical procedures</p> <p>mohs micrographic surgery</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>
<p>squamous cell carcinoma excision</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>
<p>General disorders and administration site conditions</p> <p>application site pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>
<p>chest pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 4 (0.00%)</p> <p>0</p>	<p>0 / 14 (0.00%)</p> <p>0</p>
<p>coldness general</p> <p>alternative dictionary used:</p>			

MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
edema aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	3 / 14 (21.43%)
occurrences (all)	0	0	3
edema generalized			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fatigue aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fever			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
general body pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
swelling of legs			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
infusion site erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Immune system disorders hay fever alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
Reproductive system and breast disorders nipple pain alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
Respiratory, thoracic and mediastinal disorders allergic rhinitis alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) cough alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) cough nonproductive alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) dyspnea alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) epistaxis alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) laryngeal cyst alternative dictionary used: MedDRA 17.0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0	1 / 14 (7.14%) 1 0 / 14 (0.00%) 0 0 / 14 (0.00%) 0 0 / 14 (0.00%) 0 1 / 14 (7.14%) 1

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nosebleed			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pleural effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rhinorrhea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sore throat			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
supine dyspnea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
runny nose			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
depression worsened			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
difficulty sleeping			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Investigations			

bicarbonate decreased serum alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
blood creatinine increased alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
blood glucose increased alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
blood pressure increased alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
cholesterol levels raised alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
ecg abnormal alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
fasting blood glucose abnormal alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
increased intraocular pressure alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
platelets decreased alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
potassium abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
potassium increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
renal function test abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
thyroid function test abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
uric acid level increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
weight gain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
abrasions			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
ankle sprain			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bruising			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
excoriation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
first degree burns			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
flea bite			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hematoma traumatic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
lower limb wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin laceration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
spider bite			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

sprained ankle alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
wound alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	2 / 14 (14.29%) 2
Cardiac disorders bradycardia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
heart pounding alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
tachycardia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
Nervous system disorders dizziness alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
headache alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 4 (25.00%) 2	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
headache aggravated alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
lightheadedness			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
numbness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
presyncope			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sciatica aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
body numbness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
crawling sensation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
numbness in feet			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
anemia aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
leukocytosis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
Eye disorders			
cloudy vision alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
glaucoma alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
right cataract alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
tearing decreased alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
visual acuity reduced alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	1 / 4 (25.00%) 1	0 / 14 (0.00%) 0
Gastrointestinal disorders			
abdominal cramps alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 14 (0.00%) 0
abdominal fullness alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 14 (7.14%) 1
colitis alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
diarrhea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
distress gastrointestinal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dry heaves			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dry mouth			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
heartburn			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
toothache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Hepatobiliary disorders			
portal vein phlebitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
blister			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
diaphoresis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
ecchymosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
erythema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
generalized itching			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
itching			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
localised rash			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
localized erythema			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
papular rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
pruritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
rosacea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin inflammation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
skin irritation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
skin peeling			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
chronic kidney disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
diuresis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
kidney function abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
urinary retention			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
chest wall pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
flank pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
foot pain			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
low back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
muscle cramps			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
pain in thumb			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
shoulder pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
alpha hemolytic streptococcal infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
axillary abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bacterial infection due to unspecified staphylococcus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
cellulitis of hand			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
cellulitis of leg			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
cold			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
common cold			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
conjunctivitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
dental abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
flu			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
folliculitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

head cold			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
kidney infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
leg infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
tooth infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
upper respiratory infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
urinary tract yeast infection			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
viral infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
viral labyrinthitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
viral syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
appetite lost			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
dehydration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
fasting hyperglycemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gout aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
gout flare			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hyperkalemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypoglycemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
hypoglycemia aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
hypokalemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
metabolic acidosis worsened			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
volume depletion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
volume overload			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2

Non-serious adverse events	B-LY3016859- 250mg	B-LY3016859- 750mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	11 / 12 (91.67%)	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
squamous cell carcinoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
thyroid nodule			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
blood pressure high			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
flushing of face			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
hematoma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
hypertension exacerbated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
hypertension worsened			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 13 (15.38%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
orthostatic hypotension			

alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	
Surgical and medical procedures mohs micrographic surgery alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) squamous cell carcinoma excision alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1 1 / 13 (7.69%) 2	0 / 12 (0.00%) 0 0 / 12 (0.00%) 0	
General disorders and administration site conditions application site pain alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) chest pain alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) coldness general alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) edema aggravated alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) edema generalized alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) fatigue aggravated alternative dictionary used:	0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 1 / 13 (7.69%) 1 1 / 13 (7.69%) 1	0 / 12 (0.00%) 0 1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0	

MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	2 / 12 (16.67%)	
occurrences (all)	0	2	
fever			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
general body pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
swelling of legs			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
systemic inflammatory response syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
infusion site erythema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
hay fever			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
nipple pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			

allergic rhinitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
cough			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
cough nonproductive			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
dyspnea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
epistaxis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
laryngeal cyst			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
nosebleed			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
pleural effusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
rhinorrhea			
alternative dictionary used: MedDRA 17.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>sore throat</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>supine dyspnea</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>runny nose</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p> <p>1 / 13 (7.69%)</p> <p>1</p> <p>1 / 13 (7.69%)</p> <p>1</p> <p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p>	
<p>Psychiatric disorders</p> <p>depression worsened</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>difficulty sleeping</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p> <p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p>	
<p>Investigations</p> <p>bicarbonate decreased serum</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>blood creatinine increased</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>blood glucose increased</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p> <p>0 / 13 (0.00%)</p> <p>0</p> <p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p> <p>1 / 12 (8.33%)</p> <p>1</p> <p>0 / 12 (0.00%)</p> <p>0</p>	

blood pressure increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
cholesterol levels raised			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
ecg abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
fasting blood glucose abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
increased intraocular pressure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
platelets decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
potassium abnormal			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
potassium increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
renal function test abnormal			
alternative dictionary used: MedDRA 17.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>thyroid function test abnormal</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>uric acid level increased</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>weight gain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>Injury, poisoning and procedural complications</p> <p>abrasions</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>ankle sprain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>bruising</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>excoriation</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>first degree burns</p> <p>alternative dictionary used: MedDRA 17.0</p>			

subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
flea bite			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
hematoma traumatic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
lower limb wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
skin laceration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
spider bite			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
sprained ankle			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
wound			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
bradycardia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 13 (7.69%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
heart pounding			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
tachycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 13 (15.38%)	1 / 12 (8.33%)	
occurrences (all)	2	1	
headache aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
lightheadedness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
numbness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
presyncope			
alternative dictionary used: MedDRA 17.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>sciatica aggravated</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>body numbness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>crawling sensation</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>numbness in feet</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>Blood and lymphatic system disorders</p> <p>anemia</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>anemia aggravated</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>leukocytosis</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>Eye disorders</p> <p>cloudy vision</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>glaucoma</p> <p>alternative dictionary used: MedDRA 17.0</p>			

subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
right cataract			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
tearing decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
visual acuity reduced			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
abdominal cramps			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
abdominal fullness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
colitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
diarrhea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	2 / 12 (16.67%)	
occurrences (all)	1	2	
distress gastrointestinal			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
dry heaves			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
dry mouth			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
heartburn			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
nausea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 13 (15.38%)	1 / 12 (8.33%)	
occurrences (all)	4	1	
toothache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	2	0	
Hepatobiliary disorders			
portal vein phlebitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	2 / 13 (15.38%)	0 / 12 (0.00%)
occurrences (all)	2	0
blister		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	1	0
diaphoresis		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)
occurrences (all)	1	0
ecchymosis		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
erythema		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
generalized itching		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
itching		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	2
localised rash		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	2
localized erythema		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1

<p>papular rash</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	
<p>pruritis</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	
<p>rosacea</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>skin inflammation</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	
<p>skin irritation</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>skin peeling</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	
<p>Renal and urinary disorders</p> <p>acute kidney injury</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>chronic kidney disease</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>diuresis</p> <p>alternative dictionary used: MedDRA 17.0</p>	<p>1 / 13 (7.69%)</p> <p>1</p> <p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p> <p>0 / 12 (0.00%)</p> <p>0</p>	

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>kidney function abnormal</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	
<p>urinary retention</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>Musculoskeletal and connective tissue disorders</p> <p>back pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>chest wall pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>flank pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>foot pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 13 (0.00%)</p> <p>0</p>	<p>1 / 12 (8.33%)</p> <p>1</p>	
<p>low back pain</p> <p>alternative dictionary used: MedDRA 17.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 13 (7.69%)</p> <p>1</p>	<p>0 / 12 (0.00%)</p> <p>0</p>	
<p>muscle cramps</p> <p>alternative dictionary used: MedDRA 17.0</p>			

subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
pain in thumb			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
shoulder pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Infections and infestations			
alpha hemolytic streptococcal infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
axillary abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
bacterial infection due to unspecified staphylococcus			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
cellulitis of hand			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
cellulitis of leg			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
cold		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
common cold		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
conjunctivitis		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0
dental abscess		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
flu		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
folliculitis		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
head cold		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	1
influenza		
alternative dictionary used: MedDRA 17.0		
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0

kidney infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
leg infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
tooth infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
upper respiratory infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
urinary tract yeast infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
viral infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
viral labyrinthitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	
viral syndrome alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
Metabolism and nutrition disorders appetite lost alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	
dehydration alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
fasting hyperglycemia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 12 (0.00%) 0	
gout aggravated alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
gout flare alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	2 / 12 (16.67%) 2	
hyperkalemia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 12 (0.00%) 0	
hypoglycemia alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
hypoglycemia aggravated			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
hypokalemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
metabolic acidosis worsened			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
volume depletion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
volume overload			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 March 2013	This amendment was issued before the first patient was enrolled, primarily to incorporate changes to eligibility criteria, in-house stay, and dose administration.
12 November 2013	The primary reason for this amendment was to incorporate additional blood collection for potential future evaluation of immune response.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported