



Clinical trial results:

An open label, active comparator extension trial to assess the effect of long term dosing of inclisiran and evolocumab given as subcutaneous injections in participants with high cardiovascular risk and elevated LDL-C (ORION-3)

Summary

EudraCT number	2016-003815-37
Trial protocol	GB DE NL
Global end of trial date	17 December 2021

Results information

Result version number	v1
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	MDCO-PCS-16-01
-----------------------	----------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03060577
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharmaceuticals
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@Novartis.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 December 2021
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	17 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy, safety, and tolerability of long-term dosing of inclisiran and evolocumab given as subcutaneous injections in participants with high cardiovascular risk and elevated low-density lipoprotein cholesterol (LDL-C).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 April 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 56
Country: Number of subjects enrolled	Germany: 49
Country: Number of subjects enrolled	United Kingdom: 69
Country: Number of subjects enrolled	Netherlands: 136
Country: Number of subjects enrolled	United States: 72
Worldwide total number of subjects	382
EEA total number of subjects	185

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)	198
From 65 to 84 years	182
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from 51 sites in 5 countries.

Pre-assignment

Screening details:

After completion of study MDCO-PCS-15-01, participants were screened to fulfill all inclusion and exclusion criteria.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Inclisiran-only

Arm description:

Participants received subcutaneous injections of inclisiran 300 milligrams (mg) on Day 1 and every 180 days thereafter for up to 4 years.

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

Dosage and administration details:

Participants received subcutaneous injections of inclisiran 300 milligrams (mg) on Day 1 and every 180 days thereafter for up to 4 years.

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

Dosage and administration details:

Participants received self-administered subcutaneous injections of evolocumab 140 mg on Day 1 and every 14 days thereafter until Day 336.

Arm title	Switching
------------------	-----------

Arm description:

Participants received self-administered subcutaneous injections of evolocumab 140 mg on Day 1 and every 14 days thereafter until Day 336. Then, participants received subcutaneous injections of inclisiran 300 mg on Day 360 and every 180 days thereafter for up to 4 years.

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

Dosage and administration details:

Participants received subcutaneous injections of inclisiran 300 mg on Day 360 and every 180 days thereafter for up to 4 years.

Number of subjects in period 1	Inclisiran-only	Switching
Started	290	92
Safety Analysis Set	284	87
Completed	233	80
Not completed	57	12
Adverse event, serious fatal	7	1
Consent withdrawn by subject	25	5
Physician decision	4	3
Adverse event, non-fatal	9	1
Other	8	2
Inclusion/Exclusion	1	-
Lost to follow-up	3	-

Baseline characteristics

Reporting groups

Reporting group title	Inclisiran-only
-----------------------	-----------------

Reporting group description:

Participants received subcutaneous injections of inclisiran 300 milligrams (mg) on Day 1 and every 180 days thereafter for up to 4 years.

Reporting group title	Switching
-----------------------	-----------

Reporting group description:

Participants received self-administered subcutaneous injections of evolocumab 140 mg on Day 1 and every 14 days thereafter until Day 336. Then, participants received subcutaneous injections of inclisiran 300 mg on Day 360 and every 180 days thereafter for up to 4 years.

Reporting group values	Inclisiran-only	Switching	Total
Number of subjects	290	92	382
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	145	53	198
From 65-84 years	144	38	182
85 years and over	1	1	2
Age Continuous			
Units: Year			
arithmetic mean	63.3	61.9	
standard deviation	± 11.14	± 10.56	-
Sex: Female, Male			
Units: Participants			
Female	102	37	139
Male	188	55	243
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	15	7	22
Not Hispanic or Latino	275	85	360
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Inclisiran-only
Reporting group description: Participants received subcutaneous injections of inclisiran 300 milligrams (mg) on Day 1 and every 180 days thereafter for up to 4 years.	
Reporting group title	Switching
Reporting group description: Participants received self-administered subcutaneous injections of evolocumab 140 mg on Day 1 and every 14 days thereafter until Day 336. Then, participants received subcutaneous injections of inclisiran 300 mg on Day 360 and every 180 days thereafter for up to 4 years.	

Primary: Percentage Change in LDL-C from baseline of the ORION-1 Study to Day 210 in ORION-3 (Inclisiran Arm)

End point title	Percentage Change in LDL-C from baseline of the ORION-1 Study to Day 210 in ORION-3 (Inclisiran Arm) ^{[1][2]}
End point description: Percent Change in LDL-C (beta-quantification) from baseline of the ORION-1 Study to Day 210 in ORION-3. A negative percentage score represents a reduction in LDL-C. Change is relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.	
End point type	Primary
End point timeframe: Baseline (ORION-1) and Day 210 (ORION-3)	

Notes:

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

Justification: No stats analysis was planned

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

Justification: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: Percentage Change				
arithmetic mean (confidence interval 95%)	-47.48 (-50.69 to -44.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in LDL-C from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Percentage Change in LDL-C from baseline of the ORION-1 study (Inclisiran Arm) ^[3]
-----------------	---

End point description:

Percent Change in LDL-C (beta-quantification) from baseline of the ORION-1 Study overtime in ORION-3. A negative percentage score represents a reduction in LDL-C. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type Secondary

End point timeframe:

Baseline (ORION-1) and Days 30, 360, 720, 1080 and 1044 (ORION-3)

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: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: Percentage Change				
arithmetic mean (confidence interval 95%)				
Day 30	-49.43 (-52.27 to -46.58)			
Day 360	-37.14 (-40.95 to -33.32)			
Day 720	-38.43 (-41.75 to -35.11)			
Day 1080	-51.07 (-54.75 to -47.39)			
Day 1044	-46.74 (-50.71 to -42.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in LDL-C from baseline of the ORION-1 study (Inclisiran Arm)

End point title Absolute Change in LDL-C from baseline of the ORION-1 study (Inclisiran Arm)^[4]

End point description:

Absolute Change in LDL-C (beta-quantification) from baseline of the ORION-1 Study overtime in ORION-3. A negative score represents a reduction in LDL-C. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type Secondary

End point timeframe:

Baseline (ORION-1) and Days 30, 360, 720, 1080 and 1044 (ORION-3)

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: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: mg/dL				
arithmetic mean (confidence interval 95%)				
Day 30	-62.51 (-66.76 to -58.25)			
Day 360	-47.96 (-52.56 to -43.35)			
Day 720	-49.44 (-54.25 to -44.64)			
Day 1080	-63.34 (-68.76 to -57.92)			
Day 1044	-60.04 (-65.81 to -54.27)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in PCSK9 levels from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Percentage Change in PCSK9 levels from baseline of the ORION-1 study (Inclisiran Arm) ^[5]
-----------------	--

End point description:

Percent Change in PCSK9 from baseline of the ORION-1 Study overtime in ORION-3. A negative percentage score represents a reduction in PCSK9. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (ORION-1) and Days 30, 360, 720 and 1440 (ORION-3)

Notes:

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

Justification: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: Percentage Change				
arithmetic mean (confidence interval 95%)				
Day 30	-71.80 (-73.17 to -70.44)			
Day 360	-63.79 (-65.79 to -61.80)			
Day 720	-62.17 (-64.46 to -59.88)			
Day 1440	-69.54 (-71.19 to -67.89)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in PCSK9 levels from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Absolute Change in PCSK9 levels from baseline of the ORION-1 study (Inclisiran Arm) ^[6]
-----------------	--

End point description:

Absolute Change in PCSK9 from baseline of the ORION-1 Study overtime in ORION-3. A negative score represents a reduction in PCSK9. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (ORION-1) and Days 30, 360, 720 and 1440 (ORION-3)

Notes:

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

Justification: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: ug/L				
arithmetic mean (confidence interval 95%)				
Day 30	-314.07 (-328.69 to -299.45)			
Day 360	-280.88 (-295.71 to -266.06)			
Day 720	-275.78 (-291.91 to -259.64)			
Day 1440	-314.34 (-331.22 to -297.46)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Triglycerides from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Percentage Change in Triglycerides from baseline of the ORION-1 study (Inclisiran Arm) ^[7]
-----------------	---

End point description:

Percent Change in Triglycerides from baseline of the ORION-1 Study overtime in ORION-3. A negative percentage score represents a reduction in Triglycerides. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type Secondary

End point timeframe:

Baseline (ORION-1) and Days 30, 210 and 1440 (ORION-3)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: Percentage Change				
arithmetic mean (confidence interval 95%)				
Day 30	-1.71 (-6.42 to 3.00)			
Day 210	-3.35 (-9.12 to 2.41)			
Day 1440	0.73 (-8.23 to 9.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Triglycerides from baseline of the ORION-1 study (Inclisiran Arm)

End point title Absolute Change in Triglycerides from baseline of the ORION-1 study (Inclisiran Arm)^[8]

End point description:

Absolute Change in Triglycerides from baseline of the ORION-1 Study overtime in ORION-3. A negative score represents a reduction in Triglycerides. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type Secondary

End point timeframe:

Baseline (ORION-1) and Days 30, 210 and 1440 (ORION-3)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: mg/dL				
arithmetic mean (confidence interval 95%)				
Day 30	-14.61 (-22.15 to -7.08)			

Day 210	-11.96 (-23.78 to -0.14)			
Day 1440	-14.83 (-25.75 to -3.90)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Apolipoprotein B from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Percentage Change in Apolipoprotein B from baseline of the ORION-1 study (Inclisiran Arm) ^[9]
-----------------	--

End point description:

Percent Change in Apolipoprotein B from baseline of the ORION-1 Study overtime in ORION-3. A negative percentage score represents a reduction in Apolipoprotein B. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (ORION-1) and Days 30, 210 and 1440 (ORION-3)

Notes:

[9] - 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: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: Percentage Change				
arithmetic mean (confidence interval 95%)				
Day 30	-40.43 (-42.57 to -38.29)			
Day 210	-36.65 (-39.06 to -34.23)			
Day 1440	-33.66 (-37.18 to -30.15)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Apolipoprotein B from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Absolute Change in Apolipoprotein B from baseline of the ORION-1 study (Inclisiran Arm) ^[10]
-----------------	---

End point description:

Absolute Change in Apolipoprotein B from baseline of the ORION-1 Study overtime in ORION-3. A negative score represents a reduction in Apolipoprotein B. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (ORION-1) and Days 30, 210 and 1440 (ORION-3)

Notes:

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

Justification: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: mg/dL				
arithmetic mean (confidence interval 95%)				
Day 30	-42.63 (-45.22 to -40.04)			
Day 210	-38.36 (-41.19 to -35.54)			
Day 1440	-36.26 (-40.01 to -32.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage Change in Lipoprotein-a from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Percentage Change in Lipoprotein-a from baseline of the ORION-1 study (Inclisiran Arm) ^[11]
-----------------	--

End point description:

Percent Change in Lipoprotein-a from baseline of the ORION-1 Study overtime in ORION-3. A negative percentage score represents a reduction in Lipoprotein-a. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (ORION-1) and Days 30, 210 and 1440 (ORION-3)

Notes:

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

Justification: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: Percentage Change				
arithmetic mean (confidence interval 95%)				
Day 30	-15.88 (-19.48 to -12.28)			
Day 210	9.29 (4.42 to 14.16)			

Day 1440	-5.24 (-9.86 to -0.61)			
----------	------------------------	--	--	--

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change in Lipoprotein-a from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Absolute Change in Lipoprotein-a from baseline of the ORION-1 study (Inclisiran Arm) ^[12]
-----------------	--

End point description:

Absolute Change in Lipoprotein-a from baseline of the ORION-1 Study overtime in ORION-3. A negative score represents a reduction in Lipoprotein-a. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (ORION-1) and Days 30, 210 and 1440 (ORION-3)

Notes:

[12] - 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: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	277			
Units: nmol/L				
arithmetic mean (confidence interval 95%)				
Day 30	-8.52 (-12.25 to -4.79)			
Day 210	-4.94 (-8.67 to -1.20)			
Day 1440	-4.78 (-9.63 to 0.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with ≥50% LDL-C Reduction from baseline of the ORION-1 study (Inclisiran Arm)

End point title	Number of Participants with ≥50% LDL-C Reduction from baseline of the ORION-1 study (Inclisiran Arm) ^[13]
-----------------	--

End point description:

Number of Participants with ≥50% LDL-C (beta-quantification) Reduction from baseline of the ORION-1 Study overtime in ORION-3. Changes are relative to ORION-1 Baseline, which is defined as the last available record prior to first study drug administration in ORION-1.

End point type	Secondary
----------------	-----------

End point timeframe:

Baseline (ORION-1) and Days 30, 360, 720 and 1440 (ORION-3)

Notes:

[13] - 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: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	284			
Units: Participants				
Day 30	161			
Day 360	99			
Day 720	97			
Day 1044	122			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants Reaching on Treatment LDL-C Levels of <25 mg/dL, <50 mg/dL, <70 mg/dL, and <100 mg/dL (Inclisiran Arm)

End point title	Number of Participants Reaching on Treatment LDL-C Levels of <25 mg/dL, <50 mg/dL, <70 mg/dL, and <100 mg/dL (Inclisiran Arm) ^[14]
-----------------	---

End point description:

Individual responsiveness to inclisiran is defined as the number of Participants Reaching on Treatment LDL-C Levels of <25 mg/dL, <50 mg/dL, <70 mg/dL, and <100 mg/dL at any time point.

End point type	Secondary
----------------	-----------

End point timeframe:

From the start of treatment to 30 days after end of treatment, assessed up to maximum duration of 4 years

Notes:

[14] - 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: No stats analysis was planned

End point values	Inclisiran-only			
Subject group type	Reporting group			
Number of subjects analysed	284			
Units: Participants				
LDL-C level <25 mg/dL	82			
LDL-C level <50 mg/dL	175			
LDL-C level <70 mg/dL	225			
LDL-C level <100 mg/dL	265			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were reported from the start of treatment to 30 days after end of treatment, assessed up to maximum duration of 4 years

Adverse event reporting additional description:

Any sign or symptom that occurs during the study treatment plus the 30 days post treatment

Assessment type	Systematic
-----------------	------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	18.1
--------------------	------

Reporting groups

Reporting group title	Inclisiran-only
-----------------------	-----------------

Reporting group description:

Participants received subcutaneous injections of inclisiran 300 milligrams (mg) on Day 1 and every 180 days thereafter for up to 4 years.

Reporting group title	Switching
-----------------------	-----------

Reporting group description:

Participants received self-administered subcutaneous injections of evolocumab 140 mg on Day 1 and every 14 days thereafter until Day 336. Then, participants received subcutaneous injections of inclisiran 300 mg on Day 360 and every 180 days thereafter for up to 4 years.

Serious adverse events	Inclisiran-only	Switching	
Total subjects affected by serious adverse events			
subjects affected / exposed	116 / 284 (40.85%)	40 / 87 (45.98%)	
number of deaths (all causes)	7	1	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma of colon			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma recurrent			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular lymphoma			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glottis carcinoma			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hodgkin's disease stage IV			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Invasive ductal breast carcinoma			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lipoma			

subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian fibroma			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	6 / 284 (2.11%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular seminoma (pure) stage I			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testis cancer			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			

subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Circulatory collapse			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Giant cell arteritis			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	4 / 284 (1.41%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent restenosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Prostatitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Uterine polyp			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Epistaxis			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary fibrosis			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory failure			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Hepatic enzyme increased			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulse abnormal			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Alcohol poisoning			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaesthetic complication cardiac			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Contusion			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial bones fracture			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			

subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intentional overdose			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb crushing injury			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meniscus injury			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound complication			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			

subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon rupture			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myocardial infarction			
subjects affected / exposed	6 / 284 (2.11%)	3 / 87 (3.45%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	12 / 284 (4.23%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Angina unstable			

subjects affected / exposed	5 / 284 (1.76%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve stenosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	5 / 284 (1.76%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 5	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial tachycardia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	7 / 284 (2.46%)	5 / 87 (5.75%)	
occurrences causally related to treatment / all	0 / 5	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery occlusion			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Coronary artery stenosis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve disease			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mitral valve incompetence			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carotid artery stenosis			
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Lacunar stroke			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			

subjects affected / exposed	3 / 284 (1.06%)	3 / 87 (3.45%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	4 / 284 (1.41%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epiploic appendagitis			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstructive pancreatitis			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			

subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Swollen tongue			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic fibrosis			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Calculus urinary			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress urinary incontinence			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urethral perforation			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Back pain			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	7 / 284 (2.46%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoporosis			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal stenosis			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon disorder			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Appendicitis			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis bacterial			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	6 / 284 (2.11%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 6	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cellulitis			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			

subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected bite			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal sepsis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	4 / 284 (1.41%)	2 / 87 (2.30%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (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	Inclisiran-only	Switching	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	280 / 284 (98.59%)	85 / 87 (97.70%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	13 / 284 (4.58%)	3 / 87 (3.45%)	
occurrences (all)	13	3	
Benign neoplasm of eyelid			

subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Blepharal papilloma		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Bowen's disease		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Colon adenoma		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Fibroma		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Haemangioma		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Haemangioma of liver		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Hypergammaglobulinaemia benign monoclonal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Intraductal papillary mucinous neoplasm		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lipoma		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	2	2
Malignant melanoma		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Melanocytic naevus		

subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	0	2
Meningioma		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Oesophageal papilloma		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Oral papilloma		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Ovarian fibroma		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Papilloma		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Pheochromocytoma		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Plasma cell myeloma		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Prostatic adenoma		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Seborrhoeic keratosis		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	0	2
Skin papilloma		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	0	0
Squamous cell carcinoma of skin		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Vascular disorders		

Accelerated hypertension subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0
Aortic aneurysm subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	2 / 87 (2.30%) 2
Aortic arteriosclerosis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Aortic dilatation subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Aortic stenosis subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 2	0 / 87 (0.00%) 0
Circulatory collapse subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Deep vein thrombosis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	1 / 87 (1.15%) 0
Extremity necrosis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Flushing subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	1 / 87 (1.15%) 1
Haematoma subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	6 / 284 (2.11%) 2	1 / 87 (1.15%) 0
Hypertension subjects affected / exposed occurrences (all)	49 / 284 (17.25%) 47	19 / 87 (21.84%) 20

Hypertensive crisis		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	2
Hypertensive urgency		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	2	0
Hypotension		
subjects affected / exposed	7 / 284 (2.46%)	1 / 87 (1.15%)
occurrences (all)	6	1
Iliac artery stenosis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Intermittent claudication		
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	3	0
Lymphoedema		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Orthostatic hypotension		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Peripheral arterial occlusive disease		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	4	1
Peripheral artery stenosis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Peripheral coldness		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	0
Peripheral vascular disorder		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	0
Peripheral venous disease		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0

Phlebitis			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Post thrombotic syndrome			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Thrombosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Varicophlebitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Varicose vein			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Abortion induced			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Application site erythema			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)	
occurrences (all)	5	0	
Chest discomfort			
subjects affected / exposed	6 / 284 (2.11%)	1 / 87 (1.15%)	
occurrences (all)	5	1	
Chest pain			
subjects affected / exposed	9 / 284 (3.17%)	4 / 87 (4.60%)	
occurrences (all)	6	2	
Chills			

subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	2	1
Complication of device insertion		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Crepitations		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Cyst		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	2	1
Discomfort		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Drug intolerance		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	2
Face oedema		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Fatigue		
subjects affected / exposed	29 / 284 (10.21%)	18 / 87 (20.69%)
occurrences (all)	26	14
Feeling abnormal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gait disturbance		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gravitational oedema		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Hernia		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Hunger		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Influenza like illness		
subjects affected / exposed	20 / 284 (7.04%)	5 / 87 (5.75%)
occurrences (all)	19	3
Injection site bruising		
subjects affected / exposed	8 / 284 (2.82%)	6 / 87 (6.90%)
occurrences (all)	5	9
Injection site discolouration		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	3	0
Injection site discomfort		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	0
Injection site erythema		
subjects affected / exposed	15 / 284 (5.28%)	3 / 87 (3.45%)
occurrences (all)	21	4
Injection site haematoma		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Injection site haemorrhage		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Injection site induration		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Injection site oedema		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Injection site pain		
subjects affected / exposed	15 / 284 (5.28%)	4 / 87 (4.60%)
occurrences (all)	23	4
Injection site paraesthesia		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	0	2
Injection site pruritus		

subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Injection site rash		
subjects affected / exposed	9 / 284 (3.17%)	1 / 87 (1.15%)
occurrences (all)	14	1
Injection site reaction		
subjects affected / exposed	18 / 284 (6.34%)	5 / 87 (5.75%)
occurrences (all)	33	7
Injection site urticaria		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	3	0
Injection site vesicles		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Injection site warmth		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Malaise		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	2	1
Medical device complication		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Multiple organ dysfunction syndrome		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nodule		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Non-cardiac chest pain		
subjects affected / exposed	19 / 284 (6.69%)	7 / 87 (8.05%)
occurrences (all)	17	5
Oedema		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Oedema peripheral		

subjects affected / exposed	17 / 284 (5.99%)	9 / 87 (10.34%)
occurrences (all)	11	8
Pain		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	2	0
Peripheral swelling		
subjects affected / exposed	6 / 284 (2.11%)	5 / 87 (5.75%)
occurrences (all)	4	2
Polyp		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Pyrexia		
subjects affected / exposed	7 / 284 (2.46%)	1 / 87 (1.15%)
occurrences (all)	4	1
Sensation of foreign body		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Suprapubic pain		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Swelling		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Swelling face		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Vessel puncture site bruise		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	1	0
Vessel puncture site induration		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Vessel puncture site pain		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Immune system disorders		

Allergy to animal subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Allergy to arthropod bite subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 3	0 / 87 (0.00%) 0	
Allergy to arthropod sting subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	1 / 87 (1.15%) 0	
Drug hypersensitivity subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	2 / 87 (2.30%) 1	
Food allergy subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	1 / 87 (1.15%) 2	
Hypersensitivity subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 1	0 / 87 (0.00%) 0	
Mite allergy subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Seasonal allergy subjects affected / exposed occurrences (all)	6 / 284 (2.11%) 4	5 / 87 (5.75%) 4	
Reproductive system and breast disorders			
Atrophic vulvovaginitis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Balanoposthitis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Benign prostatic hyperplasia subjects affected / exposed occurrences (all)	9 / 284 (3.17%) 8	3 / 87 (3.45%) 4	
Breast disorder female			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Breast pain		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	4	0
Breast tenderness		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Cervix disorder		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Dysmenorrhoea		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Erectile dysfunction		
subjects affected / exposed	6 / 284 (2.11%)	1 / 87 (1.15%)
occurrences (all)	2	1
Genital rash		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gynaecomastia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Haemospermia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Heavy menstrual bleeding		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Menopausal symptoms		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nipple pain		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Penile erythema		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Postmenopausal haemorrhage		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	2
Prostatitis		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	0	1
Pruritus genital		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	0
Rectocele		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Scrotal pain		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Spermatocele		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Testicular swelling		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Uterine polyp		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Vaginal dysplasia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Vulvovaginal discomfort		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Vulvovaginal pain		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Vulvovaginal pruritus		

subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	11 / 284 (3.87%)	4 / 87 (4.60%)	
occurrences (all)	13	5	
Bronchospasm			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	10 / 284 (3.52%)	2 / 87 (2.30%)	
occurrences (all)	11	3	
Cough			
subjects affected / exposed	37 / 284 (13.03%)	12 / 87 (13.79%)	
occurrences (all)	25	6	
Dry throat			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Dysphonia			
subjects affected / exposed	7 / 284 (2.46%)	2 / 87 (2.30%)	
occurrences (all)	3	2	
Dyspnoea			
subjects affected / exposed	26 / 284 (9.15%)	11 / 87 (12.64%)	
occurrences (all)	22	8	
Dyspnoea exertional			
subjects affected / exposed	11 / 284 (3.87%)	5 / 87 (5.75%)	
occurrences (all)	10	5	
Emphysema			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Epistaxis			
subjects affected / exposed	14 / 284 (4.93%)	4 / 87 (4.60%)	
occurrences (all)	11	1	
Hiccups			

subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Hypoxia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Lung infiltration		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nasal congestion		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	1	2
Nasal obstruction		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Nasal polyps		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nasal septum deviation		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Obstructive airways disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Oropharyngeal discomfort		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Oropharyngeal pain		
subjects affected / exposed	15 / 284 (5.28%)	3 / 87 (3.45%)
occurrences (all)	8	2
Oropharyngeal spasm		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Pleural effusion		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Pneumothorax		

subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Productive cough		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	0	0
Pulmonary calcification		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Pulmonary embolism		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Pulmonary hypertension		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Pulmonary mass		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	2	1
Reflux laryngitis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Respiratory disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Respiratory distress		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	4
Respiratory tract congestion		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Rhinorrhoea		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	1	2
Sinonasal obstruction		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Sinus congestion		

subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	3 / 87 (3.45%) 2	
Sinus disorder subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 1	1 / 87 (1.15%) 0	
Sinus polyp subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 2	0 / 87 (0.00%) 0	
Sleep apnoea syndrome subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 1	1 / 87 (1.15%) 1	
Sneezing subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 3	1 / 87 (1.15%) 1	
Snoring subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Throat irritation subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Tonsillar hypertrophy subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 0	
Upper respiratory tract irritation subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	2 / 87 (2.30%) 1	
Wheezing subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Psychiatric disorders Acute stress disorder subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	

Adjustment disorder with depressed mood		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Aggression		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Agitation		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Alcoholism		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Anxiety		
subjects affected / exposed	5 / 284 (1.76%)	3 / 87 (3.45%)
occurrences (all)	4	2
Anxiety disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Bruxism		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Burnout syndrome		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	0
Confusional state		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Delirium		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Depressed mood		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	2	0
Depression		

subjects affected / exposed	14 / 284 (4.93%)	2 / 87 (2.30%)
occurrences (all)	12	0
Disorientation		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Emotional disorder		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Emotional distress		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Fear		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Indifference		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Insomnia		
subjects affected / exposed	14 / 284 (4.93%)	8 / 87 (9.20%)
occurrences (all)	10	2
Intentional self-injury		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Middle insomnia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Mood altered		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Nightmare		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	2
Panic attack		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	1	1
Poor quality sleep		

subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Seasonal affective disorder subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Stress subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 1	0 / 87 (0.00%) 0	
Product issues			
Device dislocation subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Prosthetic cardiac valve failure subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Hepatobiliary disorders			
Biliary colic subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Cholecystitis subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	0 / 87 (0.00%) 0	
Cholelithiasis subjects affected / exposed occurrences (all)	9 / 284 (3.17%) 7	0 / 87 (0.00%) 0	
Cholestasis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Hepatic cyst subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 1	1 / 87 (1.15%) 1	
Hepatic fibrosis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Hepatic function abnormal			

subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	0	
Hepatic steatosis			
subjects affected / exposed	7 / 284 (2.46%)	2 / 87 (2.30%)	
occurrences (all)	6	2	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Alanine aminotransferase increased			
subjects affected / exposed	4 / 284 (1.41%)	2 / 87 (2.30%)	
occurrences (all)	4	2	
Antineutrophil cytoplasmic antibody increased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 284 (1.06%)	2 / 87 (2.30%)	
occurrences (all)	2	2	
Bilirubin conjugated increased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Blood bilirubin increased			
subjects affected / exposed	6 / 284 (2.11%)	2 / 87 (2.30%)	
occurrences (all)	4	0	
Blood calcium increased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Blood creatine phosphokinase increased			
subjects affected / exposed	12 / 284 (4.23%)	7 / 87 (8.05%)	
occurrences (all)	10	2	
Blood creatinine increased			

subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	1	1
Blood folate decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Blood glucose abnormal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Blood glucose fluctuation		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Blood glucose increased		
subjects affected / exposed	9 / 284 (3.17%)	3 / 87 (3.45%)
occurrences (all)	5	2
Blood potassium decreased		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	0	1
Blood potassium increased		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Blood pressure decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Blood pressure increased		
subjects affected / exposed	1 / 284 (0.35%)	3 / 87 (3.45%)
occurrences (all)	1	2
Blood sodium decreased		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Blood testosterone decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Blood urea increased		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Blood uric acid decreased		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Blood uric acid increased		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Blood urine present		
subjects affected / exposed	7 / 284 (2.46%)	0 / 87 (0.00%)
occurrences (all)	5	0
Body temperature increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
C-reactive protein increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Carbohydrate antigen 19-9 increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Carcinoembryonic antigen increased		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Cardiac murmur		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	1	1
Carotid bruit		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Electrocardiogram T wave abnormal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Electrocardiogram abnormal		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Eosinophil count increased		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	0	0
Gamma-glutamyltransferase		

abnormal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gamma-glutamyltransferase increased		
subjects affected / exposed	6 / 284 (2.11%)	1 / 87 (1.15%)
occurrences (all)	3	1
Glomerular filtration rate decreased		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	2	0
Glucose urine present		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Glycosylated haemoglobin increased		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Haematocrit decreased		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Haemoglobin decreased		
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)
occurrences (all)	2	1
Heart rate decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Heart rate irregular		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	3	0
Hepatic enzyme increased		
subjects affected / exposed	9 / 284 (3.17%)	2 / 87 (2.30%)
occurrences (all)	9	2
Hormone level abnormal		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
International normalised ratio decreased		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
International normalised ratio increased		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	1	0
Intraocular pressure increased		
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)
occurrences (all)	0	1
Lipoprotein (a) increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lipoprotein increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Liver function test abnormal		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	0
Liver function test increased		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Low density lipoprotein increased		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Lymphocyte count decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Mean cell haemoglobin concentration decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Mean cell haemoglobin increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Mean cell volume increased		

subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Neutrophil count increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Platelet count decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Platelet count increased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Prostatic specific antigen increased		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	2	0
Pulmonary function test decreased		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Pulse absent		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
QRS axis abnormal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
SARS-CoV-2 test positive		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Sinus rhythm		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Spirometry abnormal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Streptococcus test positive		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Thyroid function test abnormal		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Troponin T increased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Urine analysis abnormal			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Vitamin B12 decreased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Vitamin D decreased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Weight decreased			
subjects affected / exposed	2 / 284 (0.70%)	3 / 87 (3.45%)	
occurrences (all)	1	2	
Weight increased			
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
White blood cell count decreased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
White blood cell count increased			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Accidental use of placebo			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Anaemia postoperative			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Animal bite		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	0	1
Ankle fracture		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Arthropod bite		
subjects affected / exposed	7 / 284 (2.46%)	1 / 87 (1.15%)
occurrences (all)	5	0
Arthropod sting		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Back injury		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Bone contusion		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Burns second degree		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Cervical vertebral fracture		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Chest injury		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Concussion		
subjects affected / exposed	2 / 284 (0.70%)	3 / 87 (3.45%)
occurrences (all)	2	3
Contusion		
subjects affected / exposed	20 / 284 (7.04%)	10 / 87 (11.49%)
occurrences (all)	18	8
Corneal abrasion		

subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Epicondylitis		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	5	1
Eye contusion		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Eye injury		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Facial bones fracture		
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)
occurrences (all)	0	2
Fall		
subjects affected / exposed	29 / 284 (10.21%)	4 / 87 (4.60%)
occurrences (all)	34	4
Fibula fracture		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Foot fracture		
subjects affected / exposed	4 / 284 (1.41%)	2 / 87 (2.30%)
occurrences (all)	4	1
Forearm fracture		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Foreign body		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Hand fracture		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	3	0
Head injury		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	4	0
Hip fracture		

subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	1
Hypobarism		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Incisional hernia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Incorrect dose administered		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Inflammation of wound		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Injection related reaction		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Injury		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Joint dislocation		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	2	0
Joint injury		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	1
Ligament rupture		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Ligament sprain		
subjects affected / exposed	9 / 284 (3.17%)	3 / 87 (3.45%)
occurrences (all)	6	0
Limb injury		
subjects affected / exposed	3 / 284 (1.06%)	4 / 87 (4.60%)
occurrences (all)	2	4
Lip injury		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lower limb fracture		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Lumbar vertebral fracture		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Medication error		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	0
Meniscus injury		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	1	1
Muscle rupture		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Muscle strain		
subjects affected / exposed	7 / 284 (2.46%)	0 / 87 (0.00%)
occurrences (all)	7	0
Musculoskeletal injury		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Overdose		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Patella fracture		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Periorbital haematoma		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Post procedural complication		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Post procedural discomfort		

subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Post procedural haemorrhage		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Post procedural oedema		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Post procedural swelling		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Post-traumatic neck syndrome		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Post-traumatic pain		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	3	0
Postoperative ileus		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Procedural nausea		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Procedural pain		
subjects affected / exposed	6 / 284 (2.11%)	2 / 87 (2.30%)
occurrences (all)	3	2
Product dispensing error		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Radius fracture		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Reactive gastropathy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Rib fracture		

subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 3	1 / 87 (1.15%) 1
Road traffic accident subjects affected / exposed occurrences (all)	6 / 284 (2.11%) 3	3 / 87 (3.45%) 3
Skin abrasion subjects affected / exposed occurrences (all)	9 / 284 (3.17%) 6	2 / 87 (2.30%) 1
Skin laceration subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	5 / 87 (5.75%) 3
Sunburn subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 2	0 / 87 (0.00%) 0
Tendon injury subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	0 / 87 (0.00%) 0
Tendon rupture subjects affected / exposed occurrences (all)	4 / 284 (1.41%) 3	0 / 87 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1
Tibia fracture subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Tooth fracture subjects affected / exposed occurrences (all)	8 / 284 (2.82%) 5	0 / 87 (0.00%) 0
Traumatic haematoma subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 1	2 / 87 (2.30%) 1
Traumatic liver injury subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Traumatic shock		

subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Ulna fracture subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Ulnar nerve injury subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Upper limb fracture subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 1	0 / 87 (0.00%) 0	
Vaccination complication subjects affected / exposed occurrences (all)	7 / 284 (2.46%) 7	0 / 87 (0.00%) 0	
Wound subjects affected / exposed occurrences (all)	4 / 284 (1.41%) 3	0 / 87 (0.00%) 0	
Wound haemorrhage subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Wrist fracture subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 1	2 / 87 (2.30%) 2	
Wrong dose subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Congenital, familial and genetic disorders			
Corneal dystrophy subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Hydrocele subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Phimosis			

subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	0 / 87 (0.00%) 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	24 / 284 (8.45%)	12 / 87 (13.79%)	
occurrences (all)	20	10	
Angina unstable			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Aortic valve incompetence			
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)	
occurrences (all)	3	1	
Aortic valve stenosis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	0	
Arrhythmia			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Atrial fibrillation			
subjects affected / exposed	16 / 284 (5.63%)	3 / 87 (3.45%)	
occurrences (all)	14	2	
Atrial flutter			
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)	
occurrences (all)	3	2	
Atrial tachycardia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Atrial thrombosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Atrioventricular block first degree			
subjects affected / exposed	4 / 284 (1.41%)	2 / 87 (2.30%)	
occurrences (all)	3	1	
Bradycardia			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	1	1	

Bundle branch block left subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 3	0 / 87 (0.00%) 0
Bundle branch block right subjects affected / exposed occurrences (all)	4 / 284 (1.41%) 3	1 / 87 (1.15%) 1
Cardiac failure subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 1	1 / 87 (1.15%) 0
Cardiac failure congestive subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 3	1 / 87 (1.15%) 2
Cardiomyopathy subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 0
Coronary artery aneurysm subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Coronary artery disease subjects affected / exposed occurrences (all)	5 / 284 (1.76%) 5	2 / 87 (2.30%) 2
Coronary artery occlusion subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1
Coronary artery stenosis subjects affected / exposed occurrences (all)	4 / 284 (1.41%) 1	0 / 87 (0.00%) 0
Dilatation atrial subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1
Extrasystoles subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	1 / 87 (1.15%) 1
Ischaemic cardiomyopathy subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1

Left ventricular dysfunction subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1
Left ventricular failure subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	1 / 87 (1.15%) 0
Mitral valve incompetence subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	2 / 87 (2.30%) 1
Mitral valve prolapse subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	2 / 87 (2.30%) 1
Myocardial ischaemia subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	1 / 87 (1.15%) 1
Palpitations subjects affected / exposed occurrences (all)	9 / 284 (3.17%) 8	3 / 87 (3.45%) 2
Pericardial effusion subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1
Right ventricular dilatation subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1
Sinus bradycardia subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1
Supraventricular tachycardia subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	0 / 87 (0.00%) 0
Tricuspid valve incompetence subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	1 / 87 (1.15%) 1

Trifascicular block subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Ventricular extrasystoles subjects affected / exposed occurrences (all)	4 / 284 (1.41%) 2	1 / 87 (1.15%) 1	
Ventricular hypokinesia subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Ventricular tachycardia subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 3	
Nervous system disorders			
Ageusia subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Altered state of consciousness subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	1 / 87 (1.15%) 1	
Amnesia subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	1 / 87 (1.15%) 0	
Anosmia subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 2	0 / 87 (0.00%) 0	
Balance disorder subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	0 / 87 (0.00%) 0	
Burning sensation subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	0 / 87 (0.00%) 0	
Carotid arteriosclerosis subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	3 / 87 (3.45%) 2	
Carotid artery stenosis			

subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	2	1
Carpal tunnel syndrome		
subjects affected / exposed	4 / 284 (1.41%)	3 / 87 (3.45%)
occurrences (all)	4	3
Cerebral haemorrhage		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Cerebral infarction		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Cerebrovascular accident		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Cervical radiculopathy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Clonus		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Cluster headache		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Cognitive disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Cubital tunnel syndrome		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	1	1
Diabetic neuropathy		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	3	1
Disturbance in attention		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Dizziness		

subjects affected / exposed	36 / 284 (12.68%)	16 / 87 (18.39%)
occurrences (all)	27	11
Dizziness postural		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Dysarthria		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Dysgeusia		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	1
Epilepsy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Facial paralysis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Head discomfort		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Headache		
subjects affected / exposed	34 / 284 (11.97%)	14 / 87 (16.09%)
occurrences (all)	26	18
Hemiparesis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Hyperaesthesia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Hypoaesthesia		
subjects affected / exposed	8 / 284 (2.82%)	5 / 87 (5.75%)
occurrences (all)	4	3
Loss of consciousness		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lumbosacral radiculopathy		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Memory impairment		
subjects affected / exposed	5 / 284 (1.76%)	0 / 87 (0.00%)
occurrences (all)	3	0
Migraine		
subjects affected / exposed	3 / 284 (1.06%)	4 / 87 (4.60%)
occurrences (all)	2	4
Migraine with aura		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Muscle tension dysphonia		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Nerve compression		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	1
Nervous system disorder		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Neuropathy peripheral		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	2	2
Occipital neuralgia		
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)
occurrences (all)	0	2
Ophthalmic migraine		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Paraesthesia		
subjects affected / exposed	11 / 284 (3.87%)	8 / 87 (9.20%)
occurrences (all)	8	4
Parkinson's disease		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Parkinsonism		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Piriformis syndrome		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Polyneuropathy		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	3	0
Post herpetic neuralgia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Presyncope		
subjects affected / exposed	5 / 284 (1.76%)	2 / 87 (2.30%)
occurrences (all)	5	2
Radicular pain		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Radiculopathy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Restless legs syndrome		
subjects affected / exposed	3 / 284 (1.06%)	2 / 87 (2.30%)
occurrences (all)	1	3
Sciatica		
subjects affected / exposed	8 / 284 (2.82%)	6 / 87 (6.90%)
occurrences (all)	3	4
Sensory loss		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Somnolence		
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)
occurrences (all)	2	1
Syncope		
subjects affected / exposed	5 / 284 (1.76%)	2 / 87 (2.30%)
occurrences (all)	6	2
Taste disorder		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Tension headache			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Transient ischaemic attack			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)	
occurrences (all)	3	0	
Trigeminal neuralgia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Vascular dementia			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	10 / 284 (3.52%)	8 / 87 (9.20%)	
occurrences (all)	6	6	
Eosinophilia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Increased tendency to bruise			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Iron deficiency anaemia			
subjects affected / exposed	5 / 284 (1.76%)	3 / 87 (3.45%)	
occurrences (all)	4	3	
Lymphadenopathy			
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)	
occurrences (all)	1	2	
Microcytic anaemia			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences (all)	3	1	

Neutropenia			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Thrombocytopenia			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
White blood cell disorder			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
Deafness bilateral			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Deafness neurosensory			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Deafness unilateral			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Ear discomfort			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Ear pain			
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)	
occurrences (all)	4	1	
Ear swelling			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Eustachian tube dysfunction			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Excessive cerumen production			
subjects affected / exposed	2 / 284 (0.70%)	3 / 87 (3.45%)	
occurrences (all)	2	4	
Hypoacusis			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Tinnitus			
subjects affected / exposed	3 / 284 (1.06%)	4 / 87 (4.60%)	
occurrences (all)	2	3	
Vertigo			
subjects affected / exposed	13 / 284 (4.58%)	5 / 87 (5.75%)	
occurrences (all)	9	4	
Vertigo positional			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	3	0	
Vestibular disorder			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Cataract			
subjects affected / exposed	18 / 284 (6.34%)	5 / 87 (5.75%)	
occurrences (all)	20	3	
Chalazion			
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)	
occurrences (all)	0	1	
Conjunctival haemorrhage			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Corneal erosion			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Dacryostenosis acquired			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Diabetic retinopathy			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	

Diplopia		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	2	0
Dry eye		
subjects affected / exposed	5 / 284 (1.76%)	4 / 87 (4.60%)
occurrences (all)	4	3
Eczema eyelids		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Entropion		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Epiretinal membrane		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Eye irritation		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Eye oedema		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Eye swelling		
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)
occurrences (all)	0	2
Eyelid haematoma		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Eyelid ptosis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Glaucoma		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	1	2
Holmes-Adie pupil		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0

Iritis		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lacrimal mucocoele		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lacrimation decreased		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lacrimation increased		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	0	0
Macular degeneration		
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	4	3
Macular hole		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	2
Meibomian gland dysfunction		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Meibomianitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Metamorphopsia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Ocular hyperaemia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Ocular hypertension		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Photophobia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1

Retinal artery embolism			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Retinal artery occlusion			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Retinal haemorrhage			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	0	
Retinal vein occlusion			
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)	
occurrences (all)	0	2	
Retinopathy hypertensive			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Strabismus			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	2 / 284 (0.70%)	4 / 87 (4.60%)	
occurrences (all)	1	3	
Visual impairment			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Vitreous detachment			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Vitreous floaters			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Gastrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Abdominal discomfort			

subjects affected / exposed	11 / 284 (3.87%)	0 / 87 (0.00%)
occurrences (all)	10	0
Abdominal distension		
subjects affected / exposed	3 / 284 (1.06%)	2 / 87 (2.30%)
occurrences (all)	2	0
Abdominal hernia		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Abdominal pain		
subjects affected / exposed	20 / 284 (7.04%)	8 / 87 (9.20%)
occurrences (all)	15	9
Abdominal pain lower		
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	2	0
Abdominal pain upper		
subjects affected / exposed	9 / 284 (3.17%)	5 / 87 (5.75%)
occurrences (all)	7	7
Abdominal tenderness		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Anal haemorrhage		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Aphthous ulcer		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Barrett's oesophagus		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Buccal polyp		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Chronic gastritis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Colitis		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Colitis ulcerative		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Constipation		
subjects affected / exposed	22 / 284 (7.75%)	11 / 87 (12.64%)
occurrences (all)	15	10
Defaecation urgency		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Dental caries		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	1	1
Diarrhoea		
subjects affected / exposed	37 / 284 (13.03%)	13 / 87 (14.94%)
occurrences (all)	18	12
Diverticulum		
subjects affected / exposed	6 / 284 (2.11%)	6 / 87 (6.90%)
occurrences (all)	6	5
Diverticulum intestinal		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	2	2
Dry mouth		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	1
Duodenitis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Dyspepsia		
subjects affected / exposed	17 / 284 (5.99%)	2 / 87 (2.30%)
occurrences (all)	7	2
Dysphagia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Enteritis		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Eosinophilic oesophagitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Faeces discoloured		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Flatulence		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	1	2
Food poisoning		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gastric disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gastric ulcer		
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)
occurrences (all)	0	2
Gastritis		
subjects affected / exposed	5 / 284 (1.76%)	2 / 87 (2.30%)
occurrences (all)	2	1
Gastritis erosive		
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)
occurrences (all)	0	1
Gastrointestinal disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gastrointestinal motility disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gastrointestinal pain		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Gastrointestinal scarring		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gastrooesophageal reflux disease		
subjects affected / exposed	8 / 284 (2.82%)	8 / 87 (9.20%)
occurrences (all)	6	8
Gingival recession		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Glossitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Haematemesis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Haematochezia		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Haemorrhoidal haemorrhage		
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)
occurrences (all)	2	0
Haemorrhoids		
subjects affected / exposed	9 / 284 (3.17%)	6 / 87 (6.90%)
occurrences (all)	5	3
Hiatus hernia		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	2	1
Hypoaesthesia oral		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	0	0
Impaired gastric emptying		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Incarcerated umbilical hernia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Inguinal hernia		

subjects affected / exposed	10 / 284 (3.52%)	1 / 87 (1.15%)
occurrences (all)	6	2
Intestinal polyp		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Irritable bowel syndrome		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Large intestine polyp		
subjects affected / exposed	10 / 284 (3.52%)	6 / 87 (6.90%)
occurrences (all)	10	4
Leukoplakia oral		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Levator syndrome		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Malpositioned teeth		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Melaena		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Mouth ulceration		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nausea		
subjects affected / exposed	28 / 284 (9.86%)	12 / 87 (13.79%)
occurrences (all)	19	9
Oesophageal obstruction		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Oesophageal spasm		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Oesophagitis		

subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Pancreatic failure		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Pancreatic steatosis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Pancreatitis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Post-tussive vomiting		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Rectal haemorrhage		
subjects affected / exposed	3 / 284 (1.06%)	2 / 87 (2.30%)
occurrences (all)	8	0
Rectal polyp		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Salivary gland disorder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Salivary gland enlargement		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Swollen tongue		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Terminal ileitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Tooth disorder		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Toothache		

subjects affected / exposed occurrences (all)	10 / 284 (3.52%) 8	1 / 87 (1.15%) 0	
Umbilical hernia subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	1 / 87 (1.15%) 1	
Vomiting subjects affected / exposed occurrences (all)	11 / 284 (3.87%) 9	3 / 87 (3.45%) 3	
Skin and subcutaneous tissue disorders			
Acne subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Actinic elastosis subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Actinic keratosis subjects affected / exposed occurrences (all)	5 / 284 (1.76%) 6	2 / 87 (2.30%) 2	
Alopecia subjects affected / exposed occurrences (all)	4 / 284 (1.41%) 1	0 / 87 (0.00%) 0	
Blister subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	1 / 87 (1.15%) 1	
Cold sweat subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Decubitus ulcer subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Dermal cyst subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	0 / 87 (0.00%) 0	
Dermatitis subjects affected / exposed occurrences (all)	5 / 284 (1.76%) 2	2 / 87 (2.30%) 2	

<p> Dermatitis allergic subjects affected / exposed occurrences (all) </p>	<p> 0 / 284 (0.00%) 0 </p>	<p> 1 / 87 (1.15%) 0 </p>
<p> Dermatitis contact subjects affected / exposed occurrences (all) </p>	<p> 1 / 284 (0.35%) 0 </p>	<p> 0 / 87 (0.00%) 0 </p>
<p> Dry skin subjects affected / exposed occurrences (all) </p>	<p> 3 / 284 (1.06%) 3 </p>	<p> 2 / 87 (2.30%) 0 </p>
<p> Ecchymosis subjects affected / exposed occurrences (all) </p>	<p> 1 / 284 (0.35%) 1 </p>	<p> 1 / 87 (1.15%) 0 </p>
<p> Eczema subjects affected / exposed occurrences (all) </p>	<p> 9 / 284 (3.17%) 4 </p>	<p> 5 / 87 (5.75%) 3 </p>
<p> Eczema nummular subjects affected / exposed occurrences (all) </p>	<p> 1 / 284 (0.35%) 1 </p>	<p> 0 / 87 (0.00%) 0 </p>
<p> Erythema subjects affected / exposed occurrences (all) </p>	<p> 4 / 284 (1.41%) 6 </p>	<p> 0 / 87 (0.00%) 0 </p>
<p> Hand dermatitis subjects affected / exposed occurrences (all) </p>	<p> 1 / 284 (0.35%) 1 </p>	<p> 0 / 87 (0.00%) 0 </p>
<p> Hidradenitis subjects affected / exposed occurrences (all) </p>	<p> 1 / 284 (0.35%) 1 </p>	<p> 0 / 87 (0.00%) 0 </p>
<p> Hyperhidrosis subjects affected / exposed occurrences (all) </p>	<p> 4 / 284 (1.41%) 1 </p>	<p> 1 / 87 (1.15%) 0 </p>
<p> Hyperkeratosis subjects affected / exposed occurrences (all) </p>	<p> 2 / 284 (0.70%) 2 </p>	<p> 0 / 87 (0.00%) 0 </p>
<p> Ingrowing nail subjects affected / exposed occurrences (all) </p>	<p> 2 / 284 (0.70%) 2 </p>	<p> 1 / 87 (1.15%) 1 </p>

Intertrigo		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Keloid scar		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lichen planus		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	2	0
Lichenoid keratosis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nail discolouration		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nail dystrophy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Neurodermatitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Night sweats		
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)
occurrences (all)	4	1
Penile ulceration		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Petechiae		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Pityriasis rosea		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Precancerous skin lesion		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0

Pruritus		
subjects affected / exposed	16 / 284 (5.63%)	5 / 87 (5.75%)
occurrences (all)	16	6
Psoriasis		
subjects affected / exposed	5 / 284 (1.76%)	0 / 87 (0.00%)
occurrences (all)	5	0
Rash		
subjects affected / exposed	17 / 284 (5.99%)	6 / 87 (6.90%)
occurrences (all)	11	3
Rash erythematous		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	2
Rash maculo-papular		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Rash papular		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Rash pruritic		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Rosacea		
subjects affected / exposed	2 / 284 (0.70%)	3 / 87 (3.45%)
occurrences (all)	1	2
Scab		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Seborrhoeic dermatitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Skin depigmentation		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Skin discolouration		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1

Skin fissures			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Skin hyperpigmentation			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Skin induration			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Skin lesion			
subjects affected / exposed	10 / 284 (3.52%)	1 / 87 (1.15%)	
occurrences (all)	6	1	
Skin ulcer			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Stasis dermatitis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	2	1	
Trichorrhexis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Vitiligo			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Xanthoma			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Albuminuria			

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Bladder cyst		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Calculus bladder		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Calculus urinary		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	0	0
Chronic kidney disease		
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)
occurrences (all)	1	2
Cystitis noninfective		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Diabetic nephropathy		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Dysuria		
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)
occurrences (all)	3	0
Glycosuria		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Haematuria		
subjects affected / exposed	13 / 284 (4.58%)	5 / 87 (5.75%)
occurrences (all)	12	4
Hydronephrosis		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	0
Hypertonic bladder		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Incontinence		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Leukocyturia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Lower urinary tract symptoms		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	2	0
Microalbuminuria		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Micturition disorder		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Micturition urgency		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Myoglobinuria		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nephrolithiasis		
subjects affected / exposed	6 / 284 (2.11%)	0 / 87 (0.00%)
occurrences (all)	4	0
Nephropathy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nocturia		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Pollakiuria		
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	3	1
Polyuria		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Proteinuria		

subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 3	1 / 87 (1.15%) 1	
Renal artery stenosis subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Renal colic subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Renal cyst subjects affected / exposed occurrences (all)	5 / 284 (1.76%) 4	2 / 87 (2.30%) 3	
Renal failure subjects affected / exposed occurrences (all)	0 / 284 (0.00%) 0	1 / 87 (1.15%) 1	
Renal impairment subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 3	2 / 87 (2.30%) 2	
Stress urinary incontinence subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Ureteral disorder subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Urinary incontinence subjects affected / exposed occurrences (all)	2 / 284 (0.70%) 2	1 / 87 (1.15%) 0	
Urinary retention subjects affected / exposed occurrences (all)	3 / 284 (1.06%) 3	0 / 87 (0.00%) 0	
Urinary tract discomfort subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 1	0 / 87 (0.00%) 0	
Urine flow decreased subjects affected / exposed occurrences (all)	1 / 284 (0.35%) 0	0 / 87 (0.00%) 0	
Endocrine disorders			

Autoimmune thyroiditis			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Goitre			
subjects affected / exposed	1 / 284 (0.35%)	3 / 87 (3.45%)	
occurrences (all)	0	1	
Hyperthyroidism			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	6 / 284 (2.11%)	3 / 87 (3.45%)	
occurrences (all)	4	3	
Thyroid cyst			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Thyroid mass			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	58 / 284 (20.42%)	21 / 87 (24.14%)	
occurrences (all)	53	28	
Arthritis			
subjects affected / exposed	8 / 284 (2.82%)	4 / 87 (4.60%)	
occurrences (all)	5	5	
Arthritis reactive			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Articular calcification			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Axillary mass			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Back pain			

subjects affected / exposed	45 / 284 (15.85%)	16 / 87 (18.39%)
occurrences (all)	36	15
Bone atrophy		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Bone pain		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Bursitis		
subjects affected / exposed	14 / 284 (4.93%)	3 / 87 (3.45%)
occurrences (all)	10	0
Cervical spinal stenosis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Chondropathy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Coccydynia		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Costochondritis		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Dupuytren's contracture		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Enthesopathy		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Exostosis		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	2	0
Exostosis of jaw		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Femoroacetabular impingement		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Fibromyalgia		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Finger deformity		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Foot deformity		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Groin pain		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Haematoma muscle		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Intervertebral disc degeneration		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Intervertebral disc disorder		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Intervertebral disc protrusion		
subjects affected / exposed	5 / 284 (1.76%)	0 / 87 (0.00%)
occurrences (all)	5	0
Joint stiffness		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Joint swelling		
subjects affected / exposed	11 / 284 (3.87%)	1 / 87 (1.15%)
occurrences (all)	7	0
Limb discomfort		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Loose body in joint		

subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Lumbar spinal stenosis		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Muscle fatigue		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Muscle spasms		
subjects affected / exposed	20 / 284 (7.04%)	9 / 87 (10.34%)
occurrences (all)	19	8
Muscle tightness		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	2	1
Muscular weakness		
subjects affected / exposed	5 / 284 (1.76%)	3 / 87 (3.45%)
occurrences (all)	6	3
Musculoskeletal chest pain		
subjects affected / exposed	8 / 284 (2.82%)	1 / 87 (1.15%)
occurrences (all)	6	1
Musculoskeletal discomfort		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Musculoskeletal pain		
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	2	1
Musculoskeletal stiffness		
subjects affected / exposed	3 / 284 (1.06%)	3 / 87 (3.45%)
occurrences (all)	3	2
Myalgia		
subjects affected / exposed	39 / 284 (13.73%)	14 / 87 (16.09%)
occurrences (all)	28	9
Neck pain		
subjects affected / exposed	9 / 284 (3.17%)	2 / 87 (2.30%)
occurrences (all)	4	2
Osteitis		

subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	1	1
Osteoarthritis		
subjects affected / exposed	27 / 284 (9.51%)	9 / 87 (10.34%)
occurrences (all)	18	8
Osteochondrosis		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	2	0
Osteopenia		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	2	0
Osteoporosis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Pain in extremity		
subjects affected / exposed	33 / 284 (11.62%)	9 / 87 (10.34%)
occurrences (all)	29	8
Pain in jaw		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Patellofemoral pain syndrome		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Periarthritis		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Plantar fasciitis		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Polyarthritis		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Polymyalgia rheumatica		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Rheumatoid arthritis		

subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Rotator cuff syndrome		
subjects affected / exposed	5 / 284 (1.76%)	3 / 87 (3.45%)
occurrences (all)	3	2
Shoulder deformity		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Sjogren's syndrome		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Spinal deformity		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Spinal osteoarthritis		
subjects affected / exposed	8 / 284 (2.82%)	0 / 87 (0.00%)
occurrences (all)	7	0
Spinal pain		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Spinal stenosis		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Spondyloarthropathy		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Spondylolisthesis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Synovial cyst		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	0	1
Synovitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Temporomandibular joint syndrome		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Tendon discomfort			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Tendon pain			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Tendonitis			
subjects affected / exposed	6 / 284 (2.11%)	4 / 87 (4.60%)	
occurrences (all)	3	4	
Tenosynovitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Tenosynovitis stenosaurs			
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)	
occurrences (all)	0	0	
Trigger finger			
subjects affected / exposed	5 / 284 (1.76%)	0 / 87 (0.00%)	
occurrences (all)	6	0	
Winged scapula			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Abscess of eyelid			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Acarodermatitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Acute sinusitis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	

Asymptomatic bacteriuria		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Bacterial infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	2	0
Bacteriuria		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Balanitis candida		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Body tinea		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Bronchitis		
subjects affected / exposed	23 / 284 (8.10%)	6 / 87 (6.90%)
occurrences (all)	19	8
COVID-19		
subjects affected / exposed	3 / 284 (1.06%)	2 / 87 (2.30%)
occurrences (all)	3	2
Candida infection		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	1
Cellulitis		
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	2	1
Clostridium difficile infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Conjunctivitis		
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)
occurrences (all)	4	1
Corneal infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0

Coronavirus infection		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	3	0
Cystitis		
subjects affected / exposed	9 / 284 (3.17%)	6 / 87 (6.90%)
occurrences (all)	6	9
Cystitis klebsiella		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Dental fistula		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Device related infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Diarrhoea infectious		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Diverticulitis		
subjects affected / exposed	5 / 284 (1.76%)	4 / 87 (4.60%)
occurrences (all)	5	4
Ear infection		
subjects affected / exposed	2 / 284 (0.70%)	7 / 87 (8.05%)
occurrences (all)	1	7
Ear lobe infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Enterococcal infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Erysipelas		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Escherichia bacteraemia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0

External ear cellulitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	3	0
Eye infection		
subjects affected / exposed	4 / 284 (1.41%)	3 / 87 (3.45%)
occurrences (all)	3	1
Folliculitis		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Fungal infection		
subjects affected / exposed	9 / 284 (3.17%)	0 / 87 (0.00%)
occurrences (all)	6	0
Fungal skin infection		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	3	1
Furuncle		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Gastroenteritis		
subjects affected / exposed	21 / 284 (7.39%)	2 / 87 (2.30%)
occurrences (all)	12	1
Gastroenteritis bacterial		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Gastroenteritis norovirus		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Gastroenteritis viral		
subjects affected / exposed	10 / 284 (3.52%)	6 / 87 (6.90%)
occurrences (all)	8	4
Gastrointestinal viral infection		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Genital herpes		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0

Genital herpes simplex subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Genital infection fungal subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Gingivitis subjects affected / exposed	0 / 284 (0.00%)	3 / 87 (3.45%)
occurrences (all)	0	3
Helicobacter gastritis subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Helicobacter infection subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	0	1
Hepatitis C subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Herpes simplex subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Herpes zoster subjects affected / exposed	13 / 284 (4.58%)	6 / 87 (6.90%)
occurrences (all)	13	3
Hordeolum subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	7	0
Impetigo subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Infected bite subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Infection subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0

Infective exacerbation of bronchiectasis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Infective exacerbation of chronic obstructive airways disease		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Influenza		
subjects affected / exposed	53 / 284 (18.66%)	19 / 87 (21.84%)
occurrences (all)	42	20
Kidney infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	2	0
Klebsiella infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Labyrinthitis		
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)
occurrences (all)	1	0
Laryngitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Localised infection		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Lower respiratory tract infection		
subjects affected / exposed	15 / 284 (5.28%)	2 / 87 (2.30%)
occurrences (all)	23	4
Mastitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Myringitis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	0
Nail infection		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Nasal abscess		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Nasopharyngitis		
subjects affected / exposed	77 / 284 (27.11%)	23 / 87 (26.44%)
occurrences (all)	73	21
Onychomycosis		
subjects affected / exposed	7 / 284 (2.46%)	0 / 87 (0.00%)
occurrences (all)	4	0
Ophthalmic herpes zoster		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Oral candidiasis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Oral fungal infection		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Oral herpes		
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)
occurrences (all)	2	1
Oral infection		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Orchitis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Otitis externa		
subjects affected / exposed	5 / 284 (1.76%)	0 / 87 (0.00%)
occurrences (all)	3	0
Otitis media		
subjects affected / exposed	1 / 284 (0.35%)	3 / 87 (3.45%)
occurrences (all)	1	0
Paronychia		

subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Perichondritis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	2
Pharyngitis		
subjects affected / exposed	6 / 284 (2.11%)	3 / 87 (3.45%)
occurrences (all)	3	3
Pharyngitis streptococcal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Pneumonia		
subjects affected / exposed	6 / 284 (2.11%)	3 / 87 (3.45%)
occurrences (all)	4	3
Pneumonia bacterial		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Pneumonia mycoplasmal		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Pneumonia viral		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Post procedural infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Postoperative wound infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Pulpitis dental		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Pyelonephritis		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Rash pustular		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Respiratory syncytial virus infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Respiratory tract infection		
subjects affected / exposed	5 / 284 (1.76%)	3 / 87 (3.45%)
occurrences (all)	2	2
Respiratory tract infection viral		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	1	1
Retinitis		
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)
occurrences (all)	0	1
Rhinitis		
subjects affected / exposed	7 / 284 (2.46%)	2 / 87 (2.30%)
occurrences (all)	3	0
Root canal infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Sebaceous gland infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Sinusitis		
subjects affected / exposed	14 / 284 (4.93%)	7 / 87 (8.05%)
occurrences (all)	11	7
Skin infection		
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)
occurrences (all)	5	0
Soft tissue infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Staphylococcal infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Suspected COVID-19		

subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Tinea cruris		
subjects affected / exposed	0 / 284 (0.00%)	2 / 87 (2.30%)
occurrences (all)	0	2
Tonsillitis		
subjects affected / exposed	0 / 284 (0.00%)	3 / 87 (3.45%)
occurrences (all)	0	0
Tooth abscess		
subjects affected / exposed	5 / 284 (1.76%)	1 / 87 (1.15%)
occurrences (all)	3	1
Tooth infection		
subjects affected / exposed	7 / 284 (2.46%)	3 / 87 (3.45%)
occurrences (all)	4	2
Upper respiratory tract infection		
subjects affected / exposed	33 / 284 (11.62%)	9 / 87 (10.34%)
occurrences (all)	31	8
Urethritis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Urinary tract infection		
subjects affected / exposed	42 / 284 (14.79%)	12 / 87 (13.79%)
occurrences (all)	75	29
Urinary tract infection bacterial		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Vaginal infection		
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)
occurrences (all)	2	0
Varicella zoster virus infection		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Vestibular neuronitis		
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)
occurrences (all)	0	1
Viral diarrhoea		

subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Viral infection			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences (all)	2	0	
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences (all)	2	1	
Vulvovaginal candidiasis			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	2	1	
Vulvovaginal mycotic infection			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Wound infection			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	2	1	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Dehydration			
subjects affected / exposed	5 / 284 (1.76%)	0 / 87 (0.00%)	
occurrences (all)	4	0	
Diabetes mellitus			
subjects affected / exposed	40 / 284 (14.08%)	9 / 87 (10.34%)	
occurrences (all)	37	7	
Diabetes mellitus inadequate control			
subjects affected / exposed	10 / 284 (3.52%)	6 / 87 (6.90%)	
occurrences (all)	9	6	
Dyslipidaemia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Fluid retention			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	

Folate deficiency		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Fructose intolerance		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	0	0
Glucose tolerance impaired		
subjects affected / exposed	4 / 284 (1.41%)	3 / 87 (3.45%)
occurrences (all)	2	2
Gout		
subjects affected / exposed	14 / 284 (4.93%)	5 / 87 (5.75%)
occurrences (all)	18	6
Haemochromatosis		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0
Hypercholesterolaemia		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	1	0
Hyperglycaemia		
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)
occurrences (all)	2	0
Hypertriglyceridaemia		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Hyperuricaemia		
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)
occurrences (all)	2	0
Hypoglycaemia		
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)
occurrences (all)	2	2
Hypokalaemia		
subjects affected / exposed	3 / 284 (1.06%)	3 / 87 (3.45%)
occurrences (all)	3	2
Hypomagnesaemia		
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)
occurrences (all)	1	0

Hyponatraemia			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Impaired fasting glucose			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Increased appetite			
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Iron deficiency			
subjects affected / exposed	4 / 284 (1.41%)	2 / 87 (2.30%)	
occurrences (all)	3	1	
Type 2 diabetes mellitus			
subjects affected / exposed	12 / 284 (4.23%)	2 / 87 (2.30%)	
occurrences (all)	7	2	
Vitamin B12 deficiency			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Vitamin D deficiency			
subjects affected / exposed	6 / 284 (2.11%)	3 / 87 (3.45%)	
occurrences (all)	4	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 April 2017	Dose was changed from 100mg/0.5mL to 300mg/0.5mL, among other changes.
19 February 2018	Name of the active ingredient was changed to inclisiran, among other changes.
15 March 2019	Secondary and exploratory endpoints were modified, among other changes.
15 May 2019	Group 1 will receive inclisiran only and Group 2 will receive an active comparator + inclisiran, among other changes.
07 October 2020	Sponsor company changed from the Medicines company to Novartis in the protocol, among other changes

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported