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	
Phaeochromocytoma			
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	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Aortic aneurysm			
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)	
occurrences (all)	2	2	
Aortic arteriosclerosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Aortic dilatation			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Aortic stenosis			
subjects affected / exposed	3 / 284 (1.06%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Circulatory collapse			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Deep vein thrombosis			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	0	
Extremity necrosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Flushing			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Haematoma			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	6 / 284 (2.11%)	1 / 87 (1.15%)	
occurrences (all)	2	0	
Hypertension			
subjects affected / exposed	49 / 284 (17.25%)	19 / 87 (21.84%)	
occurrences (all)	47	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	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Allergy to arthropod bite			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	3	0	
Allergy to arthropod sting			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	0	
Drug hypersensitivity			
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)	
occurrences (all)	1	1	
Food allergy			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	2	
Hypersensitivity			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Mite allergy			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Seasonal allergy			
subjects affected / exposed	6 / 284 (2.11%)	5 / 87 (5.75%)	
occurrences (all)	4	4	
Reproductive system and breast disorders			
Atrophic vulvovaginitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Balanoposthitis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Benign prostatic hyperplasia			
subjects affected / exposed	9 / 284 (3.17%)	3 / 87 (3.45%)	
occurrences (all)	8	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	
Haematospermia			
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	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	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	1 / 284 (0.35%)	3 / 87 (3.45%)	
occurrences (all)	1	2	
Sinus disorder			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	1	0	
Sinus polyp			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Sleep apnoea syndrome			
subjects affected / exposed	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Sneezing			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	3	1	
Snoring			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Throat irritation			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Tonsillar hypertrophy			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	0	
Upper respiratory tract irritation			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Upper-airway cough syndrome			
subjects affected / exposed	1 / 284 (0.35%)	2 / 87 (2.30%)	
occurrences (all)	1	1	
Wheezing			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	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	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Seasonal affective disorder			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Stress			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Product issues			
Device dislocation			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Prosthetic cardiac valve failure			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Cholecystitis			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Cholelithiasis			
subjects affected / exposed	9 / 284 (3.17%)	0 / 87 (0.00%)	
occurrences (all)	7	0	
Cholestasis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Hepatic cyst			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	1	1	
Hepatic fibrosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	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	3 / 284 (1.06%)	1 / 87 (1.15%)	
occurrences (all)	3	1	
Road traffic accident			
subjects affected / exposed	6 / 284 (2.11%)	3 / 87 (3.45%)	
occurrences (all)	3	3	
Skin abrasion			
subjects affected / exposed	9 / 284 (3.17%)	2 / 87 (2.30%)	
occurrences (all)	6	1	
Skin laceration			
subjects affected / exposed	2 / 284 (0.70%)	5 / 87 (5.75%)	
occurrences (all)	2	3	
Sunburn			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Tendon injury			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Tendon rupture			
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)	
occurrences (all)	3	0	
Thermal burn			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Tibia fracture			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Tooth fracture			
subjects affected / exposed	8 / 284 (2.82%)	0 / 87 (0.00%)	
occurrences (all)	5	0	
Traumatic haematoma			
subjects affected / exposed	2 / 284 (0.70%)	2 / 87 (2.30%)	
occurrences (all)	1	1	
Traumatic liver injury			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Traumatic shock			

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

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

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

Trifascicular block			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Ventricular extrasystoles			
subjects affected / exposed	4 / 284 (1.41%)	1 / 87 (1.15%)	
occurrences (all)	2	1	
Ventricular hypokinesia			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Ventricular tachycardia			
subjects affected / exposed	0 / 284 (0.00%)	1 / 87 (1.15%)	
occurrences (all)	0	3	
Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Altered state of consciousness			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Amnesia			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	1	0	
Anosmia			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Balance disorder			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Burning sensation			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Carotid arteriosclerosis			
subjects affected / exposed	0 / 284 (0.00%)	3 / 87 (3.45%)	
occurrences (all)	0	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	10 / 284 (3.52%)	1 / 87 (1.15%)	
occurrences (all)	8	0	
Umbilical hernia			
subjects affected / exposed	2 / 284 (0.70%)	1 / 87 (1.15%)	
occurrences (all)	2	1	
Vomiting			
subjects affected / exposed	11 / 284 (3.87%)	3 / 87 (3.45%)	
occurrences (all)	9	3	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Actinic elastosis			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Actinic keratosis			
subjects affected / exposed	5 / 284 (1.76%)	2 / 87 (2.30%)	
occurrences (all)	6	2	
Alopecia			
subjects affected / exposed	4 / 284 (1.41%)	0 / 87 (0.00%)	
occurrences (all)	1	0	
Blister			
subjects affected / exposed	1 / 284 (0.35%)	1 / 87 (1.15%)	
occurrences (all)	0	1	
Cold sweat			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Decubitus ulcer			
subjects affected / exposed	1 / 284 (0.35%)	0 / 87 (0.00%)	
occurrences (all)	0	0	
Dermal cyst			
subjects affected / exposed	2 / 284 (0.70%)	0 / 87 (0.00%)	
occurrences (all)	2	0	
Dermatitis			
subjects affected / exposed	5 / 284 (1.76%)	2 / 87 (2.30%)	
occurrences (all)	2	2	

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

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