

Clinical trial results:

Study to Evaluate the Effect of Dapagliflozin on the Incidence of Worsening Heart Failure or Cardiovascular Death in Patients With Chronic Heart Failure (DAPA-HF)

Summary

EudraCT number	2016-003897-41
Trial protocol	SE CZ DE DK BG SK PL
Global end of trial date	17 July 2019
Results information	
Result version number	v1 (current)
This version publication date	22 July 2020
First version publication date	22 July 2020

Trial information

Trial identification		
Sponsor protocol code	D1699C00001	
Additional study identifiers		
ISRCTN number	-	
ClinicalTrials.gov id (NCT number)	NCT03036124	
WHO universal trial number (UTN)	-	
Notes:		

Sponsors

Sponsor organisation name	AstraZeneca AB	
Sponsor organisation address	151 85, Södertälje, Sweden,	
	AstraZeneca Information Centre, AstraZeneca, +1 8772409479, information.center@astrazeneca.com	
Scientific contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.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
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Analysis stage	Final
Date of interim/final analysis	17 July 2019
Is this the analysis of the primary	Yes

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completion data?	
Primary completion date	17 July 2019
Global end of trial reached?	Yes
Global end of trial date	17 July 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine whether dapagliflozin is superior to placebo, when added to standard of care, in reducing the incidence of CV death or a HF event (hospitalisation for HF or equivalent HF event, i.e., an urgent HF visit).

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Evidence for comparator	
Actual start date of recruitment	08 February 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	China: 237	
Country: Number of subjects enrolled	India: 237	
Country: Number of subjects enrolled	Japan: 343	
Country: Number of subjects enrolled	Taiwan: 141	
Country: Number of subjects enrolled	Vietnam: 138	
Country: Number of subjects enrolled	Bulgaria: 266	
Country: Number of subjects enrolled	Czech Republic: 210	
Country: Number of subjects enrolled	Denmark: 99	
Country: Number of subjects enrolled	Germany: 186	
Country: Number of subjects enrolled	Hungary: 250	
Country: Number of subjects enrolled	Netherlands: 135	
Country: Number of subjects enrolled	Poland: 290	
Country: Number of subjects enrolled	Russian Federation: 422	
Country: Number of subjects enrolled	Slovakia: 166	
Country: Number of subjects enrolled	Sweden: 68	
Country: Number of subjects enrolled	United Kingdom: 62	
Country: Number of subjects enrolled	Canada: 223	
Country: Number of subjects enrolled	United States: 454	
Country: Number of subjects enrolled	Argentina: 297	
Country: Number of subjects enrolled	Brazil: 520	
Worldwide total number of subjects	4744	
EEA total number of subjects	1732	

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)	1878	
From 65 to 84 years	2745	
85 years and over	121	

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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

In DAPA-HFat the first visit, i.e. the enrollment visit 1, patients were evaluated regarding the protocol mandated inclusion and exclusion criteria.

Period 1		
Period 1 title	Overall Study (overall period)	
Is this the baseline period?	Yes	
Allocation method	Randomised - controlled	
Blinding used	Double blind	
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor	
Arms		
Are arms mutually exclusive?	Yes	
Arm title	Dapa 10mg	
Arm description:		
Dapagliflozin 10 mg tablets administered orally once daily		
Arm type	Active comparator	
Investigational medicinal product name	Dapagliflozin	
Investigational medicinal product code		
Other name		
Pharmaceutical forms	Tablet	
Routes of administration	Oral use	
Dosage and administration details:		
Dapagliflozin 10 mg tablets administere	d orally once daily	
Arm title	Placebo	
Arm description:	•	
Matching placebo for dapagliflozin 10 m	g administered orally once daily	
Arm type	Placebo	
Investigational medicinal product name	Placebo	
Investigational medicinal product code		
Other name		
Pharmaceutical forms	Tablet	
	T .	

Dosage and administration details:

Routes of administration

Matching placebo for dapagliflozin 10 mg administered orally once daily

Number of subjects in period 1	Dapa 10mg	Placebo
Started	2373	2371
Completed	2368	2365
Not completed	5	6
Consent withdrawn by subject	5	4

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Oral use

Lost to follow-up	-	2

Baseline characteristics

Reporting groups		
Reporting group title	Dapa 10mg	
Reporting group description:		
Dapagliflozin 10 mg tablets administered orally once daily		
Reporting group title	Placebo	
Reporting group description:		
Matching placebo for dapagliflozin 10 mg administered orally once daily		

Reporting group values	Dapa 10mg	Placebo	Total
Number of subjects	2373	2371	4744
Age Categorical			
Units: Participants			
<=50	208	188	396
>50	2165	2183	4348
Age Continuous			
Units: Years			
arithmetic mean	66.2	66.5	
standard deviation	± 11.0	± 10.8	-
Sex: Female, Male			
Units: Participants			
Female	564	545	1109
Male	1809	1826	3635
Age, Customized			
Units: Subjects			
<=65	1032	998	2030
66 - 75	825	886	1711
>75	516	487	1003
Race/Ethnicity, Customized			
Units: Subjects			
White	1662	1671	3333
Black or African American	122	104	226
Asian	552	564	1116
Native Hawaiian or other Pacific Islander	0	2	2
American Indian or Alaska Native	3	1	4
Other	34	29	63
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	381	387	768
Not Hispanic or Latino	1992	1984	3976
Unknown or Not Reported	0	0	0
Main etiology of HF			
Units: Subjects			
Ischaemic	1316	1358	2674
Non-Ischaemic	857	830	1687
Unknown	200	183	383

Units: Subjects			
Yes	1124	1127	2251
No	1249	1244	2493
NYHA class at enrolment			
Units: Subjects			
II	1606	1597	3203
III	747	751	1498
IV	20	23	43
Type 2 diabetes at baseline			
Units: Subjects			
Yes	1075	1064	2139
No	1298	1307	2605
LVEF			
Units: Percent			
arithmetic mean	31.2	30.9	
standard deviation	± 6.7	± 6.9	-

Subject analysis sets

Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

All randomized subjects.

Reporting group values	Full Analysis Set	
	<u> </u>	
Number of subjects	4744	
Age Categorical		
Units: Participants		
<=50	396	
>50	4348	
Age Continuous		
Units: Years		
arithmetic mean	66.3	
standard deviation	± 10.9	
Sex: Female, Male		
Units: Participants		
Female		
Male		
Age, Customized		
Units: Subjects		
<=65		
66 - 75		
>75		
Race/Ethnicity, Customized		
Units: Subjects		
White		
Black or African American		
Asian		
Native Hawaiian or other Pacific Islander		
American Indian or Alaska Native		

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Other		
Ethnicity (NIH/OMB)		
Units: Subjects		
Hispanic or Latino		
Not Hispanic or Latino		
Unknown or Not Reported		
Main etiology of HF		
Units: Subjects		
Ischaemic		
Non-Ischaemic		
Unknown		
Prior HF hospitalization		
Units: Subjects		
Yes		
No		
NYHA class at enrolment		
Units: Subjects		
II		
III		
IV		
Type 2 diabetes at baseline		
Units: Subjects		
Yes		
No		
LVEF		
Units: Percent		
arithmetic mean	31.1	
standard deviation	± 6.8	

End points

End points reporting grou	ıps
Reporting group title	Dapa 10mg
Reporting group description:	
Dapagliflozin 10 mg tablets adn	ninistered orally once daily
Reporting group title	Placebo
Reporting group description:	
Matching placebo for dapaglifloz	zin 10 mg administered orally once daily
Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis
Subject analysis set description	:
All randomized subjects.	
	ed in the Composite Endpoint of CV Death, Hospitalization
Due to Heart Failure or U	rgent Visit Due to Heart Failure.
Due to Heart Failure or Un End point title	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure.
	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to
End point title End point description:	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to
End point title End point description: Primary efficacy	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to
End point title	Subjects Included in the Composite Endpoint of CV Death, Hospitalization Due to Heart Failure or Urgent Visit Due to Heart Failure.

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: Participants	386	502	386	

Statistical analysis title	Cox regression
Comparison groups	Dapa 10mg v Placebo v Full Analysis Set
Number of subjects included in analysis	7117
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65

upper limit	0.85
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Secondary: Subjects Included in the Composite Endpoint of CV Death or Hospitalization Due to Heart Failure.

nospitalization Due to near tra	mure.
End point title	Subjects Included in the Composite Endpoint of CV Death or Hospitalization Due to Heart Failure.
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
Up to 27.8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: Participants	382	495	382	

Statistical analyses

Statistical analysis title	Cox regression
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.85

Secondary: Events Included in the Composite Endpoint of Recurrent Hospitalizations Due to Heart Failure and CV Death.

End point title	Events Included in the Composite Endpoint of Recurrent Hospitalizations Due to Heart Failure and CV Death.
End point description:	
Secondary	
End point type	Secondary

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: HF events or CVD.	567	742	567	

Recurrent event analysis
Placebo v Full Analysis Set
4744
Pre-specified
superiority
= 0.0002
LWYY proportional rates model
Rate Ratio (RR)
0.75
95 %
2-sided
0.65
0.88

Secondary: Change from baseline in the KCCQ total symptom score			
End point title	Change from baseline in the KCCQ total symptom score		
End point description:			
Secondary			
End point type	Secondary		
End point timeframe:			
8 months.			

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: 1-point in the scale of 0 to 100.	2252	2235	2252	

Statistical analyses

Statistical analysis title	Win ratio analysis
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [1]
Method	Win Ratio
Parameter estimate	Win Ratio (WR)
Point estimate	1.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.11
upper limit	1.26

Notes:

[1] - The p-value is obtained from a rank ANCOVA adjusted for baseline KCCQ score and stratified by T2DM status at randomization.

Secondary: Subjects Included in the Composite Endpoint of ≥50% sustained decline in eGFR, ESRD or Renal death.

End point title	Subjects Included in the Composite Endpoint of ≥50% sustained decline in eGFR, ESRD or Renal death.
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
Up to 27.8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2371	2371	2373	
Units: Participants	28	39	28	

Statistical analysis title	Cox regression
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744

Analysis specification	Pre-specified	
Analysis type		
P-value	= 0.1681	
Method	Regression, Cox	
Parameter estimate	Hazard ratio (HR)	
Point estimate	0.71	
Confidence interval		
level	95 %	
sides	2-sided	
lower limit	0.44	
upper limit	1.16	

Secondary: Subjects Inclu	uded in the Endpoint of All-cause Mortality.
End point title	Subjects Included in the Endpoint of All-cause Mortality.
End point description:	
Secondary	
End point type	Secondary
End point timeframe:	
Up to 27.8 months.	

End point values	Dapa 10mg	Placebo	Full Analysis Set	
Subject group type	Reporting group	Reporting group	Subject analysis set	
Number of subjects analysed	2373	2371	2373	
Units: Participants	276	329	276	

Statistical analysis title	Cox regression
Comparison groups	Placebo v Full Analysis Set
Number of subjects included in analysis	4744
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0217
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	0.97

Adverse events

Adverse events information Timeframe for reporting adverse events: From first dose of study drug until last study visit Assessment type Systematic **Dictionary used** MedDRA Dictionary name 22.0 Dictionary version **Reporting groups** Reporting group title Dapa 10mg Reporting group description: -Reporting group title Placebo

Reporting	group	description:	-
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Serious adverse events	Dapa 10mg	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	895 / 2368 (37.80%)	994 / 2368 (41.98%)	
number of deaths (all causes)	287	335	
number of deaths resulting from adverse events	286	333	
Vascular disorders			
Accelerated hypertension			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angiodysplasia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
Aortic aneurysm rupture			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	

Aortic dissection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis		, , , , , , , , , , , , , , , , , , ,	
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0/0	0 / 0	
Circulatory collapse			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0/3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis		İ	
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0/3	0 / 7	
deaths causally related to treatment / all	0/0	0 / 0	
Diabetic vascular disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Dry gangrene			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism arterial			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Essential hypertension			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Extremity necrosis	į i	İ	
subjects affected / exposed		0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Haematocoele		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Haematoma		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertension		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive crisis		
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive emergency		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0/0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Hypertensive urgency		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0/0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0
Hypotension	<u> </u>	·
subjects affected / exposed	7 / 2368 (0.30%)	11 / 2368 (0.46%)
occurrences causally related to treatment / all	1 / 9	4 / 12
deaths causally related to treatment / all	0 / 0	0 / 0
Hypovolaemic shock]	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to	0 / 0	0 / 1
treatment / all	1	·

	1	1
deaths causally related to treatment / all	0/0	0 / 0
Iliac artery occlusion		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Orthostatic hypotension		
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)
occurrences causally related to treatment / all	0 / 2	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral arterial occlusive disease		
subjects affected / exposed	11 / 2368 (0.46%)	10 / 2368 (0.42%)
occurrences causally related to treatment / all	0 / 11	0 / 11
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery occlusion		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral artery stenosis	-, - 	
subjects affected / exposed	1 / 2269 (0 040/)	0 / 2368 (0.00%)
occurrences causally related to	1 / 2368 (0.04%)	,
treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral embolism		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral ischaemia		
subjects affected / exposed	9 / 2368 (0.38%)	5 / 2368 (0.21%)
occurrences causally related to treatment / all	0 / 11	0/8
deaths causally related to treatment / all	0 / 0	0 / 0
Peripheral vascular disorder	ļ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0

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Shock			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombophlebitis superficial			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis		i İ	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	1/1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous thrombosis limb	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia]	j	
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
ı	•		

Adamaganaina		1	
Adenocarcinoma of colon subjects affected / exposed	2 / 2260 /0 000/ \	2 / 2269 /0 099/ \	
occurrences causally related to	2 / 2368 (0.08%) 0 / 2	2 / 2368 (0.08%) 0 / 2	
treatment / all deaths causally related to	0.70	0 / 1	
treatment / all	0 / 0	0/1	
Basal cell carcinoma			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign breast neoplasm			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign neoplasm of bladder		i İ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Benign uterine neoplasm		i i	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder cancer	, 	, , , , , , , , , , , , , , , , , , ,	
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
		ı "/" 	
Bladder neoplasm subjects affected / exposed	1 / 2260 /0 040/ \	1 / 2260 /0.040/	
occurrences causally related to	1 / 2368 (0.04%) 0 / 1	1 / 2368 (0.04%) 0 / 1	
treatment / all deaths causally related to	0.40		
treatment / all	0 / 0	0/0	
Bladder transitional cell carcinoma subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer	-	i -	
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	

occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Breast cancer female		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Breast cancer recurrent		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brenner tumour		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cervix carcinoma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	1/1
deaths causally related to treatment / all	0 / 0	0 / 0
Cholangiocarcinoma	' 	
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences causally related to	0 / 2	0 / 0
treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Chronic lymphocytic leukaemia		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic myeloid leukaemia]	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
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	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences causally related to	0 / 1	0/3
treatment / all	I	3,3

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deaths causally related to treatment / all	0 / 1	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon neoplasm			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal adenocarcinoma		1	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer metastatic	ĺ	İ	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ductal adenocarcinoma of pancreas			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastric cancer	- , - 	, , , , , , , , , , , , , , , , , , ,	
subjects affected / exposed	3 / 3360 /0 130/\	0 / 2369 (0 000/)	
-	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastrointestinal cancer metastatic			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0/1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glioblastoma	İ	j	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0/1	0/0	
deaths causally related to			

Cliablactama multifares	I	1	
Glioblastoma multiforme subjects affected / exposed	1 / 2260 (0.040()	0 / 2260 /0 000/)	
	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatocellular carcinoma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine benign neoplasm	1	1	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Laryngeal cancer	1	ĺ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Leukaemia	1		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 1	
Leukaemia recurrent	ĺ	ĺ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0/1	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma	1	İ	
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0/1	0/2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cancer metastatic	İ		
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0/3	0/0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Lung neoplasm malignant	I	· · · · · · · · · · · · · · · · · · ·	
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)	

occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 3
Malignant melanoma		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Malignant neoplasm of unknown primary site		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Meningioma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to central nervous system		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Metastases to liver		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metastatic carcinoma of the bladder		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Metastatic malignant melanoma		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Myelodysplastic syndrome	Ī	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)

occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Myelofibrosis]	ĺ
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Nasal cavity cancer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Non-small cell lung cancer		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Oesophageal carcinoma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Ovarian cancer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Pancreatic carcinoma		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Pancreatic neoplasm	l i	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Papillary renal cell carcinoma	Į į	ĺ
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to	0/1	0/0
treatment / all	I ' I	·

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deaths causally related to treatment / all	0/0	0 / 0
Pituitary tumour benign		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Plasma cell myeloma		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0/0
Pleomorphic adenoma		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0/0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Polycythaemia vera		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0/0
deaths causally related to treatment / all	0 / 0	0 / 0
Prostate cancer		i i
subjects affected / exposed	6 / 2368 (0.25%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0/0
Rectal cancer	, , , , , , , , , , , , , , , , , , ,	' '
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to		·
treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Renal cancer		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0/1	0/0
deaths causally related to treatment / all	0 / 0	0/0
Renal neoplasm		į į
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	1/1
deaths causally related to treatment / all	0 / 1	1/1

Squamous cell carcinoma		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0/0
deaths causally related to treatment / all	0/0	0 / 0
Squamous cell carcinoma of lung subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Squamous cell carcinoma of the tongue		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Tonsil cancer		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Transitional cell carcinoma		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 1
Immune system disorders		
Heart transplant rejection		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
General disorders and administration site conditions		
Asthenia subjects affected / exposed	1 / 2269 (0.040/)	0 / 2269 (0 000/ \
occurrences causally related to	1 / 2368 (0.04%) 0 / 1	0 / 2368 (0.00%)
treatment / all	-, -	-, -
deaths causally related to treatment / all	0/0	0 / 0
Cardiac death		
Cardiac death subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)

deaths causally related to treatment / all 0 / 0 0 / 2 Chest discomfort subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
occurrences causally related to 0 / 0 0 / 1 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Chest pain
subjects affected / exposed 4 / 2368 (0.17%) 5 / 2368 (0.21%)
occurrences causally related to 0 / 4 0 / 5 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Complication associated with device
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
occurrences causally related to 0 / 0 0 / 1 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Death
subjects affected / exposed 48 / 2368 (2.03%) 48 / 2368 (2.03%)
occurrences causally related to 0 / 48 1 / 48 treatment / all
deaths causally related to treatment / all 0 / 48 1 / 48
General physical health deterioration
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)
occurrences causally related to 0 / 1 0 / 0 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Implant site haemorrhage
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)
occurrences causally related to treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Malaise
subjects affected / exposed 2 / 2368 (0.08%) 0 / 2368 (0.00%)
occurrences causally related to treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Medical device site inflammation
subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.08%)
occurrences causally related to 0 / 0 0 / 2 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0

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Multiple organ dysfunction syndrome subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to	0 / 1	0 / 1
treatment / all deaths causally related to treatment / all	0 / 1	0 / 1
Necrosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
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	6 / 2368 (0.25%)	16 / 2368 (0.68%)
occurrences causally related to treatment / all	0 / 6	0 / 19
deaths causally related to treatment / all	0 / 0	0 / 0
Pyrexia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Sudden cardiac death		
subjects affected / exposed	18 / 2368 (0.76%)	27 / 2368 (1.14%)
occurrences causally related to treatment / all	0 / 18	0 / 27
deaths causally related to treatment / all	0 / 18	0 / 27
Sudden death		
subjects affected / exposed	19 / 2368 (0.80%)	10 / 2368 (0.42%)
occurrences causally related to treatment / all	2 / 19	0 / 10
deaths causally related to treatment / all	2 / 19	0 / 10
Ulcer haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent occlusion		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Vascular stent stenosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)

occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent thrombosis	, 	,	' '
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Completed suicide			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Confusional state			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Mental status changes	ĺ		ĺ
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to	0 / 1	0 / 2	

treatment / all		
deaths causally related to treatment / all	0 / 0	0 / 0
Suicide attempt		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Bipolar I disorder		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Reproductive system and breast disorders		
Acquired hydrocele		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Adenomyosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Balanoposthitis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Benign prostatic hyperplasia		
subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 5	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Endometrial hyperplasia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0/0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Metrorrhagia	·	·
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)

	occurrences causally related to treatment / all	0 / 0	0 / 1	
	deaths causally related to treatment / all	0 / 0	0 / 0	
i	Orchitis noninfective	İ		I I
	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
	occurrences causally related to treatment / all	0 / 1	0 / 0	
	deaths causally related to treatment / all	0/0	0 / 0	
i	Ovarian cyst	İ		
	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
	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			
	Abdominal wound dehiscence			
	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
	occurrences causally related to treatment / all	0 / 0	0 / 1	
	deaths causally related to treatment / all	0/0	0 / 0	
ĺ	Accidental overdose	Î		
	subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
	occurrences causally related to treatment / all	0 / 3	0 / 2	
	deaths causally related to treatment / all	0 / 0	0 / 0	
	Acetabulum fracture			
	subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
	occurrences causally related to treatment / all	0 / 1	0 / 1	
	deaths causally related to treatment / all	0/0	0 / 0	
	Alcohol poisoning	· · · · · · · · · · · · · · · · · · ·	· [' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '
	subjects affected / exposed	1 / 2269 /0 049/3	0 / 2269 (0 000/)	
	occurrences causally related to	1 / 2368 (0.04%) 0 / 1	0 / 2368 (0.00%) 0 / 0	
	treatment / all		-	
	deaths causally related to treatment / all	0 / 0	0 / 0	
	Ankle fracture			
	subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
	occurrences causally related to treatment / all	0 / 2	0/0	
	deaths causally related to treatment / all	0/0	0 / 0	
 			· · · · · · · · · · · · · · · · · · ·	ı
	Bone contusion subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
'		•	•	. '

occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain contusion		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Brain herniation		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac valve rupture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Compression fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0/0
deaths causally related to treatment / all	0 / 0	0 / 0
Craniocerebral injury		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to	0 / 1	0 / 1
treatment / all		0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fall		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Femoral neck fracture		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	1/3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Femur fracture		
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)
occurrences causally related to	0 / 4	0 / 3
treatment / all	·	•

deaths causally related to treatment / all	,	ı ı	!
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Foot fracture subjects affected / exposed occurrences causally related to treatment / all 0 / 2368 (0.00%) 2 / 2368 (0.08%) occurrences causally related to treatment / all 0 / 0 0 / 0 0 / 0 Head injury subjects affected / exposed occurrences causally related to treatment / all 0 / 1 0 / 1 0 / 1 Hip fracture subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 0 / 0 Humerus fracture subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 0 / 0 Joint dislocation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 0 / 0 Limb injury subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 0 / 0 0 / 0 Limb injury subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 /		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally rela	Fibula fracture		
Treatment / all deaths causally related to treatment / all d	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
Foot fracture subjects affected / exposed occurrences causally related to treatment / all deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally		0 / 0	0 / 1
subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.08%) occurrences causally related to treatment / all 0 / 0 0 / 2 deaths causally related to treatment / all 0 / 0 0 / 0 Head injury subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 1 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 occurrences causally related to treatment / all 1 / 7 / 2368 (0.30%) 2 / 2368 (0.08%) occurrences causally related to treatment / all 0 / 0 0 / 0 Humerus fracture subjects affected / exposed 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 2 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Joint dislocation 1 / 2368 (0.04%) 1 / 2368 (0.04%) subjects affected / exposed 0 / 2 0 / 1 occurrences causally related to treatment / all 0 / 0 0 / 0 Limb injury subjects affected / exposed 0 / 1 0 / 0 occurrences		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all	Foot fracture		
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 1/2368 (0.04%) 1/2368 (0.04%) 1/2368 (0.04%) 0/1 0	subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
Head injury Subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 1 0		0 / 0	0 / 2
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 1 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Hip fracture subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 1 / 7 / 2368 (0.30%) 2 / 2368 (0.08%) occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 0 / 2 0 / 1 Joint dislocation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 3 1 / 2368 (0.04%) 0 / 1 Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 0 / 0 Limb injury subjects affected / exposed occurrences causally related to treatment / all 0 / 1 0 / 0 0 / 0 Limb fracture subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 0 / 0 Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 2368 (0.00%) 0 / 2368 (0.00%)		0 / 0	0 / 0
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to deaths causally related to treatment / all deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to de	Head injury		
occurrences causally related to treatment / all deaths causally related to treatment / all	- '	1 / 2368 (0.04%)	1 / 2368 (0.04%)
treatment / all deaths causally related to treatment / all Hip fracture subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Joint dislocation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all	occurrences causally related to		
Treatment / all 0 / 0 0 / 0			0 / 1
subjects affected / exposed 7 / 2368 (0.30%) 2 / 2368 (0.08%) occurrences causally related to treatment / all 1 / 7 0 / 2 deaths causally related to treatment / all 0 / 0 0 / 0 Humerus fracture subjects affected / exposed 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 2 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Joint dislocation subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 3 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Limb injury subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 1 0 / 0 Lower limb fracture subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0 0 / 0		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all	Hip fracture		
treatment / all deaths causally related to treatment / all Humerus fracture subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Joint dislocation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all	subjects affected / exposed	7 / 2368 (0.30%)	2 / 2368 (0.08%)
Treatment / all 0 / 0 0 / 0		1 / 7	0 / 2
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Joint dislocation subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%)		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all	Humerus fracture		
occurrences causally related to treatment / all deaths causally related to treatment / all	subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
deaths causally related to treatment / all 0 / 0 0 / 0 Joint dislocation subjects affected / exposed 0 0 / 3 0 / 1 coccurrences causally related to treatment / all 0 / 0 0 0 / 0 Limb injury subjects affected / exposed 0 0 / 1 0 0 / 0 Currences causally related to treatment / all 0 0 / 0 0 / 0 Limb injury subjects affected / exposed 0 0 / 1 0 / 0 coccurrences causally related to treatment / all 0 / 0 0 / 0 Lower limb fracture subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 0 Coccurrences causally related to treatment / all 0 / 0 0 / 0 Coccurrences causally related to treatment / all 0 / 0 0 / 0 / 0 Lower limb fracture subjects affected / exposed 0 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%)		-	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 0 Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%)	deaths causally related to	0 / 0	0 / 0
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 0 Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%)	loint dislocation		
occurrences causally related to treatment / all deaths causally related to treatment / all		1 / 2368 (0.04%)	1 / 2368 (0.04%)
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Limb injury subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 0 0 / 0 1 / 2368 (0.00%) 0 / 0 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 0	occurrences causally related to		,
treatment / all 0 / 0 0 / 0 Limb injury subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0 0 0 / 0 Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0	treatment / all		0 / 1
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 0 1 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%)		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all 1 / 2368 (0.04%) 1 / 2368 (0.00%) 1 / 1 0 / 0 0 / 0 0 / 0	Limb injury		
treatment / all deaths causally related to treatment / all Lower limb fracture subjects affected / exposed occurrences causally related to treatment / all o / 0 0 / 0 0 / 0 0 / 0 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 1 0 / 0	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
treatment / all 0 / 0 0 / 0 Lower limb fracture subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0		0 / 1	0 / 0
subjects affected / exposed $1/2368 (0.04\%)$ $0/2368 (0.00\%)$ occurrences causally related to treatment / all $0/0$		0 / 0	0 / 0
subjects affected / exposed $1/2368 (0.04\%)$ $0/2368 (0.00\%)$ occurrences causally related to treatment / all $0/0$	Lower limb fracture		
treatment / all		1 / 2368 (0.04%)	0 / 2368 (0.00%)
deaths causally related to		1 / 1	0 / 0
treatment / all 0 / 0 0 / 0	deaths causally related to treatment / all	0 / 0	0 / 0

Lumphan contabust Const	1		
Lumbar vertebral fracture subjects affected / exposed	1 / 2269 /0 049/	1 / 2269 /0 049/ \	
occurrences causally related to	1 / 2368 (0.04%)	1 / 2368 (0.04%) 0 / 1	
treatment / all		,	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose	1		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture	İ	· 	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0/1	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture	İ	i İ	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Poisoning	i	i i	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematoma	İ	· · · · · · · · · · · · · · · · · · ·	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria	i		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to			
treatment / all	0/0	0/0	
Post procedural haemorrhage subjects affected / exposed	1 / 2260 / 0 040/)	2 / 2260 /0.000/ \	
зарјеста апестеа / ехрозеа	1 / 2368 (0.04%)	2 / 2368 (0.08%)	

occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative wound complication		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (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	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Road traffic accident		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 1
Skin injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skull fractured base		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal compression fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Spinal fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to	0 / 0	0 / 1
treatment / all	i - 1	•

	ı		
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic injury			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	4 / 2368 (0.17%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	1 / 4	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 1	
Subdural haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0/1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Tendon injury		Ì	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn		i I	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to			
treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haematoma		· 	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to	0 / 0		

Traumatic intracranial haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatinine increased			
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood glucose increased			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood pressure increased			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ejection fraction decreased			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glomerular filtration rate decreased			i İ
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0/0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio			

increased			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary arterial pressure increased			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	5 / 2368 (0.21%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 1	
Acute myocardial infarction			
subjects affected / exposed	37 / 2368 (1.56%)	38 / 2368 (1.60%)	
occurrences causally related to treatment / all	1 / 37	1 / 40	
deaths causally related to treatment / all	1 / 11	0 / 9	
Angina pectoris subjects affected / exposed	12 / 2368 (0.51%)	12 / 2368 (0.51%)	
occurrences causally related to treatment / all	0 / 12	0 / 12	
deaths causally related to			
treatment / all	0/0	0 / 0	1

Angina unstable		
subjects affected / exposed	21 / 2368 (0.89%)	30 / 2368 (1.27%)
occurrences causally related to treatment / all	0 / 24	0 / 31
deaths causally related to treatment / all	0 / 0	0 / 0
Aortic valve incompetence		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Aortic valve stenosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Arrhythmia		
subjects affected / exposed	2 / 2368 (0.08%)	8 / 2368 (0.34%)
occurrences causally related to treatment / all	0 / 2	0 / 8
deaths causally related to treatment / all	0 / 2	0 / 5
Arteriosclerosis coronary artery		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial fibrillation		
subjects affected / exposed	26 / 2368 (1.10%)	39 / 2368 (1.65%)
occurrences causally related to treatment / all	0 / 27	0 / 43
deaths causally related to treatment / all	0 / 0	0 / 2
Atrial flutter		
subjects affected / exposed	8 / 2368 (0.34%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 9	0/3
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial tachycardia	ļ	
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Atrial thrombosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block complete		
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 3	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Atrioventricular block second degree		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradyarrhythmia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Bradycardia		
subjects affected / exposed	2 / 2368 (0.08%)	7 / 2368 (0.30%)
occurrences causally related to	0 / 2	-
treatment / all	0 / 2	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Bundle branch block left		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiac aneurysm		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (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	9 / 2368 (0.38%)	10 / 2368 (0.42%)
occurrences causally related to treatment / all	0 / 9	0 / 10
deaths causally related to treatment / all	0 / 6	0 / 7
Cardiac disorder		ĺ
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to	0 / 1	0 / 0
treatment / all	ı	

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deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	262 / 2368 (11.06%)	351 / 2368 (14.82%)	
occurrences causally related to treatment / all	8 / 380	8 / 523	
deaths causally related to treatment / all	0 / 53	1 / 76	
Cardiac failure acute			
subjects affected / exposed	42 / 2368 (1.77%)	59 / 2368 (2.49%)	
occurrences causally related to treatment / all	1 / 58	3 / 75	
deaths causally related to treatment / all	0 / 11	0 / 13	
Cardiac failure chronic			
subjects affected / exposed	27 / 2368 (1.14%)	33 / 2368 (1.39%)	
occurrences causally related to treatment / all	0 / 32	0 / 46	
deaths causally related to treatment / all	0 / 8	0 / 9	
Cardiac failure congestive			
subjects affected / exposed	65 / 2368 (2.74%)	70 / 2368 (2.96%)	
occurrences causally related to treatment / all	2 / 102	4 / 106	
deaths causally related to treatment / all	1 / 9	0 / 13	
Cardiac tamponade			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac valve disease			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardio-respiratory arrest		ĺ	
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0 000/)	
	-	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 2	
Cardiogenic shock			
subjects affected / exposed	9 / 2368 (0.38%)	15 / 2368 (0.63%)	
occurrences causally related to treatment / all	0 / 10	0 / 16	
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Cardiomyopathy		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Cardiopulmonary failure		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 0
Cardiorenal syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1
Cardiovascular insufficiency		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Chronic left ventricular failure		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Congestive cardiomyopathy		
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Coronary artery disease	ĺ	
subjects affected / exposed	9 / 2368 (0.38%)	8 / 2368 (0.34%)
occurrences causally related to treatment / all	0 / 10	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 1
Coronary artery insufficiency	ĺ	
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 2
Coronary artery stenosis]	ĺ
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)

occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Extrasystoles		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Frederick's syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Ischaemic cardiomyopathy	İ	
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to	0.40	0.40
treatment / all	0/0	0/0
Left ventricular dysfunction		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Left ventricular failure		
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0
Low cardiac output syndrome		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Mitral valve incompetence	Į į	
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Myocardial fibrosis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to	0 / 1	0 / 0
treatment / all	i - 1	•

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deaths causally related to treatment / all 0 / 1 0 / 0	
Myocardial infarction	
subjects affected / exposed 16 / 2368 (0.68%) 17 / 2368 (0.72	2%)
occurrences causally related to 1 / 16 0 / 17 treatment / all	
deaths causally related to treatment / all 0 / 7 0 / 7	
Myocardial ischaemia	
subjects affected / exposed 3 / 2368 (0.13%) 4 / 2368 (0.179)	%)
occurrences causally related to 0 / 3 0 / 4 treatment / all	
deaths causally related to treatment / all 0 / 1 0 / 2	
Palpitations	
subjects affected / exposed 1 / 2368 (0.04%) 2 / 2368 (0.089)	_{%)}
occurrences causally related to 0 / 1 0 / 2	
treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Pericardial effusion	
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.049)	%)
occurrences causally related to $0\ /\ 1$ $0\ /\ 1$ treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Pericarditis	
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.049)	%)
occurrences causally related to 0 / 1 0 / 1 treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Prosthetic cardiac valve thrombosis	
subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.089)	_{%)}
occurrences causally related to 0 / 0 0 / 2 treatment / all	-
deaths causally related to treatment / all 0 / 0 0 / 0	
Pulseless electrical activity	į
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.009)	_{%)}
occurrences causally related to 0 / 1 0 / 0 treatment / all	
deaths causally related to treatment / all 0 / 1 0 / 0	
Right ventricular failure	j
subjects affected / exposed 1 / 2368 (0.04%) 3 / 2368 (0.139)	%)
occurrences causally related to 0 / 1 0 / 3 treatment / all	
deaths causally related to treatment / all 0 / 1 0 / 0	

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Sinus node dysfunction subjects affected / exposed	2 / 2260 /0 420/ \	1 / 2260 /0.040/	
	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0/0	0 / 0	
Tachyarrhythmia			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia	İ	İ	
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0/0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Torsade de pointes	ĺ		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tricuspid valve incompetence	I		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Ventricular arrhythmia	I	į į	
subjects affected / exposed	6 / 2368 (0.25%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0/6	0/8	
deaths causally related to treatment / all	0 / 0	0 / 2	
Ventricular extrasystoles	İ		
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation	İ		I i
subjects affected / exposed	11 / 2368 (0.46%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 11	0 / 7	
deaths causally related to treatment / all	0 / 4	0 / 2	
Ventricular tachyarrhythmia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	34 / 2368 (1.44%)	54 / 2368 (2.28%)	
occurrences causally related to treatment / all	1 / 41	1 / 65	
deaths causally related to treatment / all	0 / 1	0 / 2	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 2368 (0.13%)	11 / 2368 (0.46%)	
occurrences causally related to treatment / all	0 / 4	1 / 13	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood loss anaemia			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to	0 / 1	0 / 2	
treatment / all			
deaths causally related to treatment / all	0/0	0 / 0	
Coagulopathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Febrile neutropenia			l i
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia	i I	· · · · · · · · · · · · · · · · · · ·	
subjects affected / exposed	2 / 2368 (0 000/)	0 / 3368 (0 000/)	
	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to	1 / 2	0 / 0	

treatment / all			
deaths causally related to treatment / all	0 / 0	0/0	
Leukopenia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
espiratory, thoracic and mediastinal sorders			
Acute pulmonary oedema			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	7 / 2368 (0.30%)	14 / 2368 (0.59%)	
occurrences causally related to treatment / all	0 / 9	0 / 16	
deaths causally related to treatment / all	0 / 1	0 / 3	
Aspiration			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0/0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Asthma]	İ	
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0/2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiectasis]	İ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
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Chronic obstructive pulmonary disease			

occurrences causally related to treatment / all	0 / 16	0 / 34	
deaths causally related to treatment / all	0/0	0 / 0	
Chronic respiratory failure	Í		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
Dyspnoea			
subjects affected / exposed	4 / 2368 (0.17%)	6 / 2368 (0.25%)	
occurrences causally related to			
treatment / all	0 / 4	1 / 6	
deaths causally related to treatment / all	0/0	0 / 0	
Eosinophilic pneumonia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Epistaxis			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0/0	0 / 0	
Haemoptysis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia	İ		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Interstitial lung disease	1		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung cyst			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

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deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngeal lesion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pleurisy			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
Pleuritic pain		Ĺ	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0/1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumomediastinum		İ	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pneumonia aspiration		i i	
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 2	
Pneumonitis	' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	' ' I 	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to	1 / 2368 (0.04%)	0 / 0	
treatment / all deaths causally related to	0.40	0.40	
treatment / all	0/0	0/0	
Pneumothorax subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/1	0 / 1	
deaths causally related to	0 / 0		

Pneumothorax spontaneous	[
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0/0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary alveolar haemorrhage		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary congestion		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary embolism		
subjects affected / exposed	7 / 2368 (0.30%)	14 / 2368 (0.59%)
occurrences causally related to treatment / all	0 / 7	1 / 14
deaths causally related to treatment / all	0 / 3	1 / 6
Pulmonary hypertension		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary mass		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary oedema		
subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)
occurrences causally related to treatment / all	0 / 4	0 / 5
deaths causally related to treatment / all	0/0	0 / 1
Pulmonary toxicity		ĺ
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Pulmonary vasculitis]	ĺ
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

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occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Respiratory failure			1
subjects affected / exposed	3 / 2368 (0.13%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0/3	0 / 7	
deaths causally related to treatment / all	0 / 2	0 / 4	
Nervous system disorders			
Brain injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Brain stem infarction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 3	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
Cerebellar stroke	1		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to			
treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Cerebral haematoma			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral haemorrhage	Į į		ĺ
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to	0 / 0	0 / 2	

treatment / all		
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebral infarction		
subjects affected / exposed	8 / 2368 (0.34%)	11 / 2368 (0.46%)
occurrences causally related to treatment / all	2 / 9	1 / 12
deaths causally related to treatment / all	0 / 3	0 / 0
Cerebral ischaemia		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0
Cerebral thrombosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Cerebrovascular accident		
subjects affected / exposed	7 / 2368 (0.30%)	5 / 2368 (0.21%)
occurrences causally related to treatment / all	0 / 7	0 / 5
deaths causally related to treatment / all	0 / 2	0 / 3
Diabetic ketoacidotic hyperglycaemic coma		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0
Dizziness		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Embolic stroke		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Epilepsy]	ĺ
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1

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deaths causally related to treatment / all	0 / 0	0 / 0	
Facial paralysis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial		l I	
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Haemorrhagic stroke		l I	
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 3	0 / 1	
Haemorrhagic transformation stroke			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Headache		l I	
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic cerebral infarction		i i	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
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Ischaemic stroke subjects affected / exposed	24 / 2368 (1.01%)	26 / 2368 (1.10%)	
occurrences causally related to treatment / all	0 / 26	0 / 28	
deaths causally related to			

	1	l l	
Loss of consciousness			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0/0	
Neuralgia	1		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parkinson's disease	l i		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peroneal nerve palsy	1		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post herpetic neuralgia	1	i İ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope	İ		
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0/0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica	j i	i İ	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage	i i		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Syncope		
subjects affected / exposed	7 / 2368 (0.30%)	13 / 2368 (0.55%)
occurrences causally related to treatment / all	1 / 7	4 / 14
deaths causally related to treatment / all	0 / 0	0 / 0
Transient ischaemic attack		
subjects affected / exposed	13 / 2368 (0.55%)	7 / 2368 (0.30%)
occurrences causally related to treatment / all	0 / 13	0 / 7
deaths causally related to treatment / all	0/0	0 / 0
Vascular dementia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Vascular encephalopathy		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0/0
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery occlusion		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebral artery stenosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Vertebrobasilar insufficiency]	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
IIIrd nerve paresis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to	0/1	0/0
treatment / all	I , -	

treatment / all Eye disorders Angle closure glaucoma subjects affected / exposed occurrences causally related to	0 / 0 1 / 2368 (0.04%) 0 / 1	0 / 0	
Angle closure glaucoma subjects affected / exposed			
occurrences causally related to	0 / 1	_	
treatment / all		0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cataract			
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 4	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glaucoma			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Optic ischaemic neuropathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal artery occlusion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Strabismus	j		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	

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deaths causally related to			
treatment / all	0 / 0	0 / 0	
Vision blurred subjects affected / exposed			
	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vitreous haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
ar and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
Vertigo positional	ĺ		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 1	0/3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vestibular disorder	i I		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
astrointestinal disorders			
Abdominal adhesions			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal distension			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain	j		
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	

I			
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Chronic gastritis		I	
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to	•		
treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	4 / 2368 (0.17%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal		İ	
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
	_		
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal haemorrhagic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage		İ	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to			

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Duodenal ulcer perforation subjects affected / exposed	1 / 2260 /0 040/ >	1 / 2260 /0.040/	
	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspepsia			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Gastric haemorrhage	ĺ	ĺ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer	1	i i	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage	1	i i	
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis	İ	i İ	
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive	j	i i	
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastritis haemorrhagic		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiectasia		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal angiodysplasia		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0/0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal disorder		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal haemorrhage		
subjects affected / exposed	4 / 2368 (0.17%)	7 / 2368 (0.30%)
occurrences causally related to treatment / all	0 / 5	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal obstruction		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Gastrointestinal polyp haemorrhage		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gastrointestinal ulcer		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to	0 / 0	0 / 1
treatment / all	!	ı

deaths causally related to treatment / all 0 / 0 0 / 0 Gastrooesophageal reflux disease subjects affected / exposed 0 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 0 occurrences causally related to treatment / all 0 / 0 0 / 0 Haematemesis subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	%)
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Haematemesis	%)
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 Haematemesis	%)
treatment / all deaths causally related to treatment / all Haematemesis	
treatment / all 0 / 0 0 / 0 Haematemesis	
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	
	%)
occurrences causally related to 0 / 0 0 / 1 treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Haematochezia	- 1
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%)	%)
occurrences causally related to 0 / 1 0 / 1 treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Haemorrhoidal haemorrhage	i
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	%)
occurrences causally related to 0 / 0 0 / 1 treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Ileus	i
subjects affected / exposed 2 / 2368 (0.08%) 0 / 2368 (0.00%)	_%)
occurrences causally related to 0 / 2 0 / 0 treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Ileus paralytic	i
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	_{%)}
occurrences causally related to $0/0$ $0/1$	´
treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Inguinal hernia	
subjects affected / exposed 9 / 2368 (0.38%) 5 / 2368 (0.21%)	%)
occurrences causally related to 0 / 9 0 / 5 treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	
Intestinal haemorrhage	
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	%)
occurrences causally related to 0 / 0 0 / 1 treatment / all	
deaths causally related to treatment / all 0 / 0 0 / 0	

Intestinal ischaemia		1	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction		ĺ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0/0	
Intestinal perforation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine polyp		ĺ	
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Megacolon			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Melaena			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery thrombosis		ĺ	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea		ĺ	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	

occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Obstructive pancreatitis	İ		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Oesophageal ulcer	ľ		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to			
treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic mass	i İ		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to			
treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 1	
Pancreatitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 6	1 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pancreatitis chronic	· 	· · · · · · · · · · · · · · · · · · ·	
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
Rectal polyp	į į		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	

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deaths causally related to treatment / all	0 / 0	0 / 0	
Retroperitoneal haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0/0	0 / 0	
Small intestinal obstruction	1		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Thrombosis mesenteric vessel	1		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to		, , ,	
treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0/0	
Umbilical hernia			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage	1		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to			
treatment / all	0/0	0/0	
Vomiting			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0/1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stenosis	İ		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to		0 / 1	
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deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary dilatation			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute]	i i	
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis		i	
subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0/3	0 / 5	
deaths causally related to treatment / all	0 / 1	0 / 0	
·			
Cholecystitis acute subjects affected / exposed	6 / 2368 (0.25%)	8 / 2368 (0.34%)	
occurrences causally related to	-		
treatment / all	0 / 6	0 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Cholecystitis chronic			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis		l İ	
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to			

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Cryptogenic cirrhosis subjects affected / exposed	1 / 2262 /2 5 221	0 / 2250 / 2 2253	
	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder enlargement			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis	l i	İ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatic failure		ĺ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis		Ì	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0/1	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute]	i İ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic hepatitis		' 	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Jaundice		· 	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

	_	_	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Jaundice cholestatic	Ì		i İ
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (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	23 / 2368 (0.97%)	46 / 2368 (1.94%)	
occurrences causally related to treatment / all	2 / 25	5 / 49	
deaths causally related to treatment / all	0/3	0 / 1	
Anuria			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder neck obstruction	Ì		i İ
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0/0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease	İ		i I I
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 4	1 / 10	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis noninfective	j		
subjects affected / exposed	1 / 2260 (0.040/)	0 / 3360 (0 000/)	
	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
End stage renal disease			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	1/1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria	İ	-	
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to	0 / 2	0 / 1	
, , , , ,	1 0,2	l	l l

treatment / all			
deaths causally related to treatment / all Hydronephrosis	0 / 0	0 / 0	
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	1/2	0 / 0	
deaths causally related to treatment / all	0/0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0/0	
Nephropathy toxic			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postrenal failure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prerenal failure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal artery stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal colic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	

deaths causally related to treatment / all 0 / 0 0 / 0 Renal cyst subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0 0 / 0 Renal disorder subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0 deaths causally related to treatment / all 0 / 0 Renal disorder subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Renal disorder subjects affected / exposed 0 / 2368 (0.00%) 7 / 2368 (6.60%) 0 / 0 1 / 2368 (0.04%)
treatment / all deaths causally related to treatment / all Renal disorder subjects affected / exposed 0 / 2368 (0.00%) 7 0 0 0 / 0 1 / 2368 (0.04%)
treatment / all 0 / 0 0 / 0 Renal disorder
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
(0.007.0)
occurrences causally related to $0 / 0$ $0 / 1$ treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Renal failure
subjects affected / exposed 8 / 2368 (0.34%) 8 / 2368 (0.34%)
occurrences causally related to 1 / 8 1 / 9 treatment / all
deaths causally related to treatment / all 1 / 2 0 / 0
Renal impairment
subjects affected / exposed 7 / 2368 (0.30%) 13 / 2368 (0.55%)
occurrences causally related to 1 / 7 0 / 14 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Renal injury
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)
occurrences causally related to treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Ureterolithiasis
subjects affected / exposed 3 / 2368 (0.13%) 0 / 2368 (0.00%)
3 / 2300 (0.13 %)
occurrences causally related to treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Urethral stenosis
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%)
occurrences causally related to 0 / 1 0 / 1 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Urinary retention
subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.08%)
occurrences causally related to 0 / 0 0 / 2 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0

Device Insulation Insulat				
Subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatm				
occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally				
treatment / all deaths causally related to treatment / all Device fallure 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 2 0 /		1 / 2368 (0.04%)	0 / 2368 (0.00%)	
Device failure Subjects affected / exposed O / 2368 (0.00%) 2 / 2368 (0.08%) O / 2		0 / 1	0 / 0	
Subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occur		0 / 0	0 / 0	
Occurrences causally related to treatment / all Device inappropriate shock delivery subjects affected / exposed occurrences causally related to treatment / all O / 0	Device failure			
treatment / all deaths causally related to treatment / all Device inappropriate shock delivery subjects affected / exposed occurrences causally related to treatment / all deaths causally related to deaths causally re	subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
Device inappropriate shock delivery subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to o		0 / 0	0 / 2	
Subjects affected / exposed		0 / 0	0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 Device lead issue subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 Device malfunction subjects affected / exposed 0 / 2368 (0.00%) 0 / 0 Device malfunction subjects affected / exposed 0 / 2368 (0.04%) 0 / 0 Device malfunction subjects affected / exposed 0 / 2368 (0.04%) 0 / 0 Device malfunction subjects affected / exposed 0 / 2368 (0.04%) 0 / 0 Device malfunction subjects affected / exposed 0 / 2368 (0.00%) 0 / 0 Device malfunction 0 / 1 0 / 2 Device malfunction subjects affected / exposed 0 / 1 / 2368 (0.04%) 0 / 0 Device malfunction 0 / 1 0 / 2 Device malfunction 0 / 1 0 / 2 Device malfunction 0 / 1 0 / 2 Device malfunction 0 / 1 0 / 2 Device malfunction 0 / 1 0 / 0 Device malfunction 0 / 1 0 / 0 Device malfunction 0 / 1 0 / 0 Device malfunction 0 / 1 0 / 0 Device malfunction 0 / 0 0 / 0 Device malfunction 0 / 1 0 / 0 Device malfunction 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0	Device inappropriate shock delivery			
treatment / all deaths causally related to treatment / all 0 / 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
treatment / all		0 / 0	0 / 1	
Subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occur		0 / 0	0 / 0	
occurrences causally related to treatment / all deaths causally related to deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to deaths causa	Device lead issue			
treatment / all deaths causally related to treatment / all Device malfunction subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Device malfunction 1 / 2368 (0.04%) 2 / 2368 (0.08%) 0 / 0 1 / 2368 (0.04%) 0 / 0 1 / 2368 (0.04%) 0 / 0 Deviction and subcutaneous tissue disorders Blister subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
Device malfunction 1 / 2368 (0.04%) 2 / 2368 (0.08%)		0 / 0	0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Lead dislodgement subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all		0 / 0	0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to tre	Device malfunction			
treatment / all deaths causally related to treatment / all Lead dislodgement subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Skin and subcutaneous tissue disorders Blister subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Decubitus ulcer subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
treatment / all		0 / 1	0 / 2	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Skin and subcutaneous tissue disorders Blister subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Decubitus ulcer subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to		0 / 0	0 / 0	
occurrences causally related to treatment / all deaths causally related to treatment / all	Lead dislodgement			
treatment / all deaths causally related to treatment / all O / 0 Skin and subcutaneous tissue disorders Blister subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Decubitus ulcer subjects affected / exposed 1 / 2368 (0.04%) 0 / 1 0 / 1 0 / 1 Decubitus ulcer subjects affected / exposed 1 / 2368 (0.04%) 0 / 0 0 / 0 0 / 0 Decubitus ulcer subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
treatment / all 0 / 0 0 / 0 Skin and subcutaneous tissue disorders Blister subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 0 Decubitus ulcer subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 1 0 / 0 occurrences causally related to treatment / all 0 / 0 0 / 0		0 / 0	0 / 1	
Blister subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 1 0 / 1 deaths causally related to treatment / all Decubitus ulcer subjects affected / exposed 1 / 2368 (0.04%) 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0		0 / 0	0 / 0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Decubitus ulcer subjects affected / exposed occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Skin and subcutaneous tissue disorders			
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 0 / 0 Decubitus ulcer subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 1 0 / 0				
treatment / all deaths causally related to treatment / all Decubitus ulcer subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
treatment / all 0 / 0 0 / 0 Decubitus ulcer subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all deaths causally related to		0 / 1	0 / 1	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to		0/0	0 / 0	
occurrences causally related to treatment / all deaths causally related to	Decubitus ulcer			
treatment / all deaths causally related to	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
		0 / 1	0 / 0	
		0 / 0	0 / 0	

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Dermatitis allergic		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 3	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Drug eruption		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Eczema		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Petechiae		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Psoriasis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Rash		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0/0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0
Skin necrosis		'
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)

occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer		· 	
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urticaria			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (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			
Arthritis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis reactive			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
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	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dupuytren's contracture		-	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
	ı	ı	1
Gouty arthritis subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
	'		•

Occurrences causally related to treatment / all deaths causally re			
Intervertebral disc degeneration subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all de		0 / 1	0 / 3
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all deaths causally related to deaths causally related to treatment / all deaths causally related to deaths causally related to		0 / 0	0 / 0
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all deaths causally related to deaths causally related to treatment / all deaths causally related to deaths causally related to	Intervertebral disc degeneration		
treatment / all deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths c		1 / 2368 (0.04%)	0 / 2368 (0.00%)
Intervertebral disc protrusion subjects affected / exposed occurrences causally related to treatment / all deaths causally related to do / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 / 0 /		0 / 1	0 / 0
subjects affected / exposed 2 / 2368 (0.08%) 2 / 2368 (0.08%) occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 2 0 / 3 Joint effusion subjects affected / exposed 0 / 0 0 / 0 subjects affected / exposed 0 / 1 0 / 0 occurrences causally related to treatment / all 0 / 0 0 / 0 Lumbar spinal stenosis 2 / 2368 (0.08%) 1 / 2368 (0.04%) subjects affected / exposed 0 / 2 0 / 1 occurrences causally related to treatment / all 0 / 0 0 / 0 Muscle spasms 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 1 0 / 0 deaths causally related to treatment / all 0 / 0 0 / 0 Muscular weakness subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0 0 / 0 Musculoskeletal chest pain subjects affected / exposed 0 / 0 0 / 0 occurrences causally related to treatment / all 0 / 0 0 / 0 deaths causally related to treatment / all		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occ	Intervertebral disc protrusion		
treatment / all deaths causally related to treatment / all Joint effusion subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Lumbar spinal stenosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally related to deaths causally	subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
deaths causally related to treatment / all Joint effusion subjects affected / exposed occurrences causally related to treatment / all deaths causally related to deaths causally		0 / 2	0 / 3
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (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 occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 2 0 / 1 Muscle spasms subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 0 / 0 Muscular weakness subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 0 / 0 Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 0 / 2 0 / 4 Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 0 0 / 2368 (0.00%)	deaths causally related to	0 / 0	0 / 0
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Lumbar spinal stenosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Muscle spasms subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Muscular weakness subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / a	Joint effusion		
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Lumbar spinal stenosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment		1 / 2368 (0.04%)	0 / 2368 (0.00%)
Lumbar spinal stenosis 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 2 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Muscle spasms 0 / 2 0 / 2 subjects affected / exposed 0 / 0 0 / 0 occurrences causally related to treatment / all 0 / 1 0 / 0 deaths causally related to treatment / all 0 / 0 0 / 0 Muscular weakness 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 1 0 / 0 deaths causally related to treatment / all 0 / 0 0 / 0 Musculoskeletal chest pain subjects affected / exposed 2 / 2368 (0.08%) 4 / 2368 (0.17%) occurrences causally related to treatment / all 0 / 2 0 / 4 deaths causally related to treatment / all 0 / 0 0 / 0 Musculoskeletal pain subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0 0 / 0		0 / 1	0 / 0
Lumbar spinal stenosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Muscle spasms subjects affected / exposed occurrences causally related to treatment / all deaths causally related to 0 / 0 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 0 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to		0 / 0	0 / 0
subjects affected / exposed 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 2 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Muscle spasms 0 / 0 0 / 0 0 / 0 occurrences causally related to treatment / all 0 / 1 0 / 0 0 / 0 Muscular weakness 0 / 0 0 / 0 0 / 0 0 / 0 Muscular weakness 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 0 occurrences causally related to treatment / all 0 / 1 0 / 0 0 / 0 Musculoskeletal chest pain subjects affected / exposed 2 / 2368 (0.08%) 4 / 2368 (0.17%) 0 / 4 occurrences causally related to treatment / all 0 / 2 0 / 4 0 / 0 Musculoskeletal pain subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) occurrences causally related to treatment / all 0 / 0 0 / 0 0 / 0 0 / 0	·		0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all		2 / 2260 /0 000/)	1 / 2260 (0.040()
treatment / all deaths causally related to treatment / all Muscle spasms subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Muscular weakness subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all do / 0 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0 0 / 0			
Muscle spasms 1 / 2368 (0.04%) 0 / 0 occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 1 0 / 0 Muscular weakness subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all do / 0 0 / 2 0 / 4 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to treatment / all subjects affected / exposed occurrences causally related to occurrences causally	treatment / all	0 / 2	0 / 1
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Muscular weakness subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all oldenty 2	•	0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all	Muscle spasms		
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Muscular weakness subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all O / 0 4 / 2368 (0.04%) O / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 0 0 / 0 0 / 2368 (0.00%) O / 2368 (0.00%) O / 2368 (0.00%)	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
Muscular weakness subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all subjects affected / exposed occurrences causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all subjects affected / exposed occurrences causally related to treatment / all Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 0 0 / 2 0 / 2 0 / 2 0 / 2 0 / 0 0 / 0	•	0 / 1	0 / 0
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 1 / 2368 (0.04%) 0 / 2		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Musculoskeletal pain subjects affected / exposed occurrences causally related to 1 / 2368 (0.04%) 0 / 2 368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%)	Muscular weakness		
treatment / all deaths causally related to treatment / all Musculoskeletal chest pain subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 1 / 2368 (0.04%) O / 2 368 (0.00%) Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 0 0 / 0 0 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 0	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
treatment / all 0 / 0 0 / 0 Musculoskeletal chest pain subjects affected / exposed 0 / 2 2/ 2368 (0.08%) 4 / 2368 (0.17%) 0 / 2 0 / 4 0 / 4 0 / 4 0 / 4 0 / 2 0 / 4 0 / 4 0 / 2 0 / 4 0 / 4 0 / 2 0 / 4 0 / 2 0 / 4 0 / 2 0 / 2 0 / 4 0 / 2 0 / 2 0 / 4 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%) 0 / 2 368 (0.00%)		0 / 1	0 / 0
subjects affected / exposed 2 / 2368 (0.08%) 4 / 2368 (0.17%) occurrences causally related to treatment / all 0 / 0 0 / 0 Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 1 0 / 0		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all Musculoskeletal pain subjects affected / exposed occurrences causally related to 0 / 2 0 / 4 0 / 0 0 / 0 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%)	Musculoskeletal chest pain		
treatment / all deaths causally related to treatment / all Musculoskeletal pain subjects affected / exposed occurrences causally related to 1 / 2368 (0.04%) 0 / 0 0 / 0 0 / 0	subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
treatment / all		0 / 2	0 / 4
subjects affected / exposed $1/2368 (0.04\%)$ 0 / 2368 (0.00%) occurrences causally related to $0/1$ 0 / 0		0 / 0	0 / 0
occurrences causally related to $0/1$ $0/0$	Musculoskeletal pain		
	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
	occurrences causally related to treatment / all	0 / 1	0 / 0

deaths causally related to treatment / all 0 / 0 0 / 0 Myalgia subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.08%)
subjects affected / exposed
subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.08%)
occurrences causally related to 0 / 0 0 / 3 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Osteoarthritis
subjects affected / exposed 5 / 2368 (0.21%) 7 / 2368 (0.30%)
occurrences causally related to 0 / 6 0 / 7 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Osteonecrosis of jaw
subjects affected / exposed
occurrences causally related to 0 / 1 0 / 1 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Pain in extremity
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
occurrences causally related to 0 / 0 0 / 1 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Pleural mass
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)
occurrences causally related to treatment / all 0 / 0
deaths causally related to treatment / all 0 / 0 0 / 0
Polymyalgia rheumatica
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
occurrences causally related to $0/0$ $0/1$
treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Pseudarthrosis
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)
occurrences causally related to 0 / 0 0 / 1 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0
Spinal pain
subjects affected / exposed 2 / 2368 (0.08%) 1 / 2368 (0.04%)
occurrences causally related to 0 / 3 0 / 1 treatment / all
deaths causally related to treatment / all 0 / 0 0 / 0

Spinal stenosis	1	1	I
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondyloarthropathy		l	!
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spondylolisthesis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypothyroidism			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0/0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	10 / 2368 (0.42%)	8 / 2368 (0.34%)	
occurrences causally related to treatment / all	0 / 10	0/8	
deaths causally related to treatment / all	0 / 0	0 / 0	
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Diabetes mellitus		
subjects affected / exposed	5 / 2368 (0.21%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetes mellitus inadequate control		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketoacidosis		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic ketosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic metabolic decompensation		
subjects affected / exposed	6 / 2368 (0.25%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 6	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid overload		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Fluid retention		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Gout		
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Hyperglycaemia		
subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)

occurrences causally related to treatment / all	0 / 3	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemic hyperosmolar			
nonketotic syndrome		. , ,	[
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to treatment / all	0/1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia	Ì		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypomagnesaemia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemia		- 	
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	1/3	1/2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis	İ		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to	1/2	0 / 0	
treatment / all	1/2	Ι	

	1	1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Steroid diabetes			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0/0	0/0	
nfections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 2260 (0 000/)	1 / 2360 (0.040/)	
	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to	0 / 0	0 / 1	
treatment / all			
deaths causally related to treatment / all	0 / 0	0/0	
Abscess			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess limb			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0/0	
Acute sinusitis		İ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to		0/0	
treatment / all	0 / 1	0/0	

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deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis		İ	
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0/0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Biliary sepsis	,	· · · · · · · · · · · · · · · · · · ·	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis subjects affected / exposed	12 / 2260 /0 510/	6 / 2260 /0 250/	
	12 / 2368 (0.51%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 13	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis infective			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to			

0 11 111	1		
Cellulitis subjects affected / exposed	0 / 2250 /0 200/	10 (2250 (0 420))	
occurrences causally related to	9 / 2368 (0.38%)	0 / 12	
treatment / all	0,11		
deaths causally related to treatment / all	0 / 0	0/0	
Cellulitis gangrenous			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervicitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridial infection	İ	į į	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis	İ	i i	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection		i i	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis	1		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2368 (0.00%)	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dengue fever			
subjects affected / exposed	1 / 2260 (0.040/)	1 / 2369 (0.040/)	
	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	

occurrences causally related to treatment / all	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic foot infection	i İ	
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Diabetic gangrene		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Disseminated tuberculosis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1
Diverticulitis		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 1	0 / 2
deaths causally related to treatment / all	0/0	0 / 0
Endocarditis		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 1	0 / 0
Endocarditis bacterial		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1
Endotoxic shock		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Enteritis infectious		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to	0 / 0	0 / 1
treatment / all	1	•

	I	1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterococcal bacteraemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epididymitis			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Erysipelas			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences causally related to			
treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fournier's gangrene			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Furuncle			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gangrene	·		
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0 / 5	1 / 7	
deaths causally related to treatment / all	0 / 0	0 / 1	
Gastroenteritis			
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences causally related to treatment / all	0/3	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis rotavirus	· 		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to			

Gastrointestinal infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal viral infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster oticus			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Implant site infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected dermal cyst			l
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infectious pleural effusion]		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Influenza]	
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0
Intestinal sepsis		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Liver abscess		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Localised infection		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Lower respiratory tract infection		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0
Lung infection		
subjects affected / exposed	4 / 2368 (0.17%)	4 / 2368 (0.17%)
occurrences causally related to treatment / all	0 / 7	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0
Lyme disease		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Mediastinal abscess		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to	0/1	0/0
treatment / all	I , -	

•	1	1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis tuberculous			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0/0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metapneumovirus infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis		· 	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis	·	· · · · · · · · · · · · · · · · · · ·	
subjects affected / exposed	0 / 2269 (0 000/)	1 / 2269 (0.040/)	
	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0/0	0 / 0	
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	7 / 2368 (0.30%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	1/9	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to			

Otitic modia acute		
Otitis media acute subjects affected / exposed	0 / 2260 /0 000/ \	1 / 2260 /0.040/ \
occurrences causally related to	0 / 2368 (0.00%) 0 / 0	1 / 2368 (0.04%) 0 / 1
treatment / all	3, 3	0,1
deaths causally related to treatment / all	0 / 0	0 / 0
Perichondritis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Periodontitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0
Peritonitis		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 1
Peritonsillar abscess		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0/0	0/1
deaths causally related to treatment / all	0 / 0	0 / 0
Pneumonia		
subjects affected / exposed	76 / 2368 (3.21%)	82 / 2368 (3.46%)
occurrences causally related to treatment / all	0 / 83	1 / 87
deaths causally related to treatment / all	0 / 9	0 / 8
Pneumonia bacterial	· 	
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences causally related to treatment / all	0/1	0/2
deaths causally related to treatment / all	0 / 0	0 / 0
Postoperative abscess	· · · · · · · · · · · · · · · · · · ·	· · · · · · · · · · · · · · · · · · ·
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1
deaths causally related to		
treatment / all	0 / 0	0 / 0
Postoperative wound infection		
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)

occurrences causally related to treatment / all deaths causally related to treatment / all		·	treatment / all
treatment / all 0 / 0 0 / 0 Pulmonary sepsis subjects affected / exposed 1 / 2368 (0.04%) 2 / 2368 (0.08%) occurrences causally related to treatment / all 0 / 1 0 / 0 Pulmonary tuberculosis subjects affected / exposed occurrences causally related to treatment / all 0 / 0 2 / 2368 (0.08%) occurrences causally related to treatment / all 0 / 0 0 / 2	0 / 0		1 11 11 11
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Pulmonary tuberculosis subjects affected / exposed occurrences causally related to treatment / all 0 / 1 0 / 2 7 / 2368 (0.08%) 0 / 0 0 / 0 2 / 2368 (0.08%) 0 / 0 2 / 2368 (0.08%) 0 / 2368 (0.00%) 0 / 2 2 / 2368 (0.08%)	ì	0/0	
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Pulmonary tuberculosis subjects affected / exposed occurrences causally related to treatment / all 0 / 1 0 / 2 7 / 2368 (0.08%) 0 / 0 0 / 0 2 / 2368 (0.08%) 0 / 0 2 / 2368 (0.08%) 0 / 2368 (0.00%) 0 / 2 2 / 2368 (0.08%)		İ	Pulmonary sensis
treatment / all deaths causally related to treatment / all Pulmonary tuberculosis subjects affected / exposed occurrences causally related to treatment / all 0 / 1	2 / 2368 (0.08%)	1 / 2368 (0.04%)	, ,
treatment / all 0 / 1 0 / 0 Pulmonary tuberculosis subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.08%) occurrences causally related to treatment / all 0 / 0 0 / 2	0 / 2	0 / 1	
subjects affected / exposed 0 / 2368 (0.00%) 2 / 2368 (0.08%) occurrences causally related to treatment / all 0 / 0 0 0 / 2	0 / 0	0 / 1	
occurrences causally related to treatment / all			Pulmonary tuberculosis
occurrences causally related to 0 / 0 0 / 2 treatment / all	2 / 2368 (0.08%)	0 / 2368 (0.00%)	subjects affected / exposed
treatment / all 0 / 0 0 / 0	0 / 0	0 / 0	deaths causally related to
Pyelocystitis	j	i İ İ	Pvelocystitis
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to 0 / 1 0 / 0 treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all 0 / 0 0 / 0	0 / 0	0 / 0	
Pyelonephritis			Pvelonephritis
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%)	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to 1 / 1 1 1 / 1 treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all 0 / 0 0 / 0	0 / 0	0 / 0	•
Pyelonephritis acute			Pyelonephritis acute
subjects affected / exposed 2 / 2368 (0.08%) 0 / 2368 (0.00%)	0 / 2368 (0.00%)	2 / 2368 (0.08%)	, ,
occurrences causally related to $\frac{1}{2}$, , ,	occurrences causally related to
treatment / all	0 / 0	1/2	
deaths causally related to treatment / all 0 / 0 0 / 0	0 / 0	0 / 0	
Rectal abscess			Rectal abscess
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)	0 / 2368 (0.00%)	1 / 2368 (0.04%)	subjects affected / exposed
occurrences causally related to 0 / 1 0 / 0 treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all 0 / 0 0 / 0	0 / 0	0 / 0	
Renal abscess	į	i İ	Renal abscess
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences causally related to 0 / 0 0 / 2 treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all 0 / 0 0 / 0	0 / 0	0 / 0	
Renal cyst infection			Renal cyst infection
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	1 / 2368 (0.04%)	0 / 2368 (0.00%)	·
occurrences causally related to 0 / 0 0 / 1 treatment / all	· · · · · · · · · · · · · · · · · · ·		

deaths causally related to treatment / all Respiratory syncytial virus infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / a	ı	į i	j i
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 1 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Respiratory tract infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 3 5 / 2368 (0.21%) Rickettsiosis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 Sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally rela	Respiratory syncytial virus infection		
treatment / all deaths causally related to treatment / all deaths ca	subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
Respiratory tract infection Subjects affected / exposed Occurrences causally related to treatment / all Occurrences causally related to tr		0 / 1	0 / 1
subjects affected / exposed occurrences causally related to treatment / all deaths causa		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all	Respiratory tract infection		
treatment / all deaths causally related to treatment / all occurrences causall	subjects affected / exposed	3 / 2368 (0.13%)	5 / 2368 (0.21%)
Treatment / all		0 / 3	0 / 5
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causally related to occurrences causall	Rickettsiosis		
occurrences causally related to treatment / all deaths causally related to treatment / all		1 / 2368 (0.04%)	0 / 2368 (0.00%)
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Sepsis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	occurrences causally related to		-
Sepsis Subjects affected / exposed 13 / 2368 (0.55%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.59%) 14 / 2368 (0.34%) 16 / 2368 (0.34%) 16 / 2368 (0.34%) 16 / 2368 (0.34%) 16 / 2368 (0.34%) 16 / 2368 (0.34%) 16 / 2368 (0.34%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.04%) 16 / 2368 (0.00%) 16 /		0,1	, , ,
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Septic shock subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Sinusitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Skin infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all		0 / 0	0 / 0
occurrences causally related to treatment / all deaths causally related to treatment / all 1 / 5 0 / 6 Septic shock subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 9 0 / 9 0 / 9 Sinusitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 1 Skin infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to deaths causally r	Sepsis		
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Septic shock subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Sinusitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all	subjects affected / exposed	13 / 2368 (0.55%)	14 / 2368 (0.59%)
treatment / all 1 / 5 0 / 6 Septic shock 8 / 2368 (0.34%) 8 / 2368 (0.34%) occurrences causally related to treatment / all 0 / 9 0 / 9 deaths causally related to treatment / all 0 / 4 0 / 1 Sinusitis 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Skin infection 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 1 deaths causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 0 deaths causally related to treatment / all 0 / 0 0 / 0		1 / 13	0 / 14
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Sinusitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Skin infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all		1 / 5	0 / 6
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 4 0 / 1 Sinusitis subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 1 deaths causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 Skin infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 0 Skin infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 1 Staphylococcal infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 0 Staphylococcal infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 0 Staphylococcal infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 0 Occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Septic shock		
treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Sinusitis subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Skin infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all o/0 1 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 0 0 / 1 Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	subjects affected / exposed	8 / 2368 (0.34%)	8 / 2368 (0.34%)
treatment / all 0 / 4 0 / 1 Sinusitis subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 0 / 0 Skin infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 0 / 1 deaths causally related to treatment / all 0 / 0 0 0 / 0 Staphylococcal infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all deaths causally related to		0 / 9	0 / 9
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Skin infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to		0 / 4	0 / 1
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Skin infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Sinusitis		
occurrences causally related to treatment / all deaths causally related to treatment / all 0 / 0 0 / 0 Skin infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 O / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 0 O / 2368 (0.00%) 0 / 0 O / 2368 (0.00%) 0 / 0		0 / 2368 (0.00%)	1 / 2368 (0.04%)
deaths causally related to treatment / all 0 / 0 0 / 0 Skin infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all 0 / 0 0 / 1			
Skin infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to	deaths causally related to	0 / 0	0 / 0
subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all deaths causally related to treatment / all deaths causally related to	Skin infection	· 	
occurrences causally related to treatment / all deaths causally related to treatment / all Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to occurrences causally related to treatment / all deaths causally related to		0 / 2368 (0.00%)	1 / 2368 (0.04%)
deaths causally related to treatment / all 0 / 0 0 / 0 Staphylococcal infection subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences causally related to treatment / all deaths causally related to	occurrences causally related to		
Staphylococcal infection subjects affected / exposed occurrences causally related to treatment / all deaths causally related to	deaths causally related to	0 / 0	0 / 0
subjects affected / exposed $0 / 2368 (0.00\%)$ $1 / 2368 (0.04\%)$ occurrences causally related to treatment / all deaths causally related to			
treatment / all deaths causally related to	• •	0 / 2368 (0.00%)	1 / 2368 (0.04%)
		0 / 0	0 / 1
treatment / all 0 / 0 0 0 / 0	deaths causally related to treatment / all	0 / 0	0 / 0

Cubdianhracmaticaharra		I	
Subdiaphragmatic abscess subjects affected / exposed	1 / 2260 /0 040/	1 / 2260 (0.040()	
	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic candida			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tuberculosis		I	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection		I	
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	11 / 2368 (0.46%)	17 / 2368 (0.72%)	
occurrences causally related to treatment / all	7 / 13	4 / 17	
deaths causally related to treatment / all	0 / 0	0 / 1	
Urinary tract infection staphylococcal		ĺ	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis		į į	
subjects affected / exposed	4 / 2368 (0.17%)	7 / 2368 (0.30%)	
occurrences causally related to treatment / all	0 / 4	1/7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection	· 	i	
subjects affected / exposed	5 / 2368 (0.21%)	0 / 2368 (0.00%)	

occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HIV infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Dapa 10mg	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	928 / 2368 (39.19%)	955 / 2368 (40.33%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	88 / 2368 (3.72%)	73 / 2368 (3.08%)	
occurrences (all)	98	81	
Accelerated hypertension			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Aortic aneurysm			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Aortic dilatation			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Aortic stenosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Aortic thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Arterial stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Circulatory collapse			

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Deep vein thrombosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Dry gangrene			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Flushing			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Haematoma			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences (all)	1	4	
Hypertension			
subjects affected / exposed	17 / 2368 (0.72%)	19 / 2368 (0.80%)	
occurrences (all)	19	21	
Hypertensive crisis			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Hypertensive urgency			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Hypovolaemic shock			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences (all)	0	3	
Intermittent claudication			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Lymphatic fistula			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Orthostatic hypotension			
subjects affected / exposed	10 / 2368 (0.42%)	5 / 2368 (0.21%)	
occurrences (all)	10	5	
Dowinhowal autorial application discussion			
Peripheral arterial occlusive disease	I	<u> </u>	

subjects affected / exposed	7 / 2368 (0.30%)	3 / 2368 (0.13%)	
occurrences (all)	7	3	
Peripheral artery occlusion			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Peripheral artery stenosis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Peripheral coldness			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Peripheral embolism			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Peripheral ischaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Peripheral venous disease			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	3	0	
Phlebitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Poor peripheral circulation			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Raynaud's phenomenon			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Subclavian artery stenosis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Subclavian vein thrombosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Thrombophlebitis superficial			

subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
, ,			
Varicose ulceration			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Varicose vein			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	
Vasculitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
	_	, and the second	
Venous thrombosis subjects affected / exposed			
	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Neoplasms benign, malignant and			
unspecified (incl cysts and polyps) Abdominal neoplasm			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Anogenital warts subjects affected / exposed	1 / 2269 (0 040/)	0 / 2269 (0 000/)	
occurrences (all)	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
decarrences (an)	1	0	
Basal cell carcinoma			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Benign lung neoplasm			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Danima manulassa afia la la la la la la la la la la la la la			
Benign neoplasm of adrenal gland subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
(4)		1	
Bladder cancer			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Bladder transitional cell carcinoma			
	1	l	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

1	Bowen's disease			
Colon adenoma subjects affected / exposed occurrences (all) Colon cancer subjects affected / exposed occurrences (all) Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) Description of the color	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Colon cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Seyelid tumour subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Lipoma subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Lung neoplasm subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Squamous cell carcinoma 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%)	occurrences (all)	1	0	
Occurrences (all) 0 1 Colon cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Occurrences (all) 0 2 Eyelid tumour subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Occurrences (all) 0 1 Lipoma subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 0 / 2368 (0.04%) Occurrences (all) 1 0 Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Occurrences (all) 1 0 Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Occurrences (all) 1 0 Renal cancer subjects affected / exposed occurrences (all) 1 0 Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Occurrences (all) 0 1 0				
Colon cancer subjects affected / exposed occurrences (all) 1	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) Eyelid tumour subjects affected / exposed occurrences (all) O 2 Eyelid tumour subjects affected / exposed occurrences (all) O 1 Lipoma subjects affected / exposed occurrences (all) O 1 Lipoma subjects affected / exposed occurrences (all) O 1 Lung neoplasm subjects affected / exposed occurrences (all) O 1 Plasma cell myeloma subjects affected / exposed occurrences (all) Prostate cancer subjects affected / exposed occurrences (all) Prostate cancer subjects affected / exposed occurrences (all) 1 2368 (0.04%) O / 2368 (0.00%)	occurrences (all)	0	1	
Occurrences (all) 1 0 Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) 2 Eyelid tumour subjects affected / exposed occurrences (all) 0 1/2368 (0.00%) 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.04%) 0 1/2368 (0.00%) 1/2368 (0.00%) 0 1/2368 (0.00%)				
Cutaneous T-cell lymphoma recurrent subjects affected / exposed occurrences (all) Eyelid tumour subjects affected / exposed occurrences (all) Description occurrences (all) Lipoma subjects affected / exposed occurrences (all) Description occurrences (all) Lung neoplasm subjects affected / exposed occurrences (all) Description occurrences (all) Plasma cell myeloma subjects affected / exposed occurrences (all) Prostate cancer subjects affected / exposed occurrences (all) Prostate cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Description occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Description occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Description occurrences (all) Description occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all) Description occurrences (all occurrences	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
recurrent subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 2 Eyelid tumour subjects affected / exposed occurrences (all) 0 1 Lipoma subjects affected / exposed occurrences (all) 0 1 Lipoma subjects affected / exposed occurrences (all) 0 1 Lung neoplasm subjects affected / exposed occurrences (all) 1 0 0 1 Plasma cell myeloma subjects affected / exposed occurrences (all) 1 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	occurrences (all)	1	0	
occurrences (all) Eyelid tumour subjects affected / exposed occurrences (all) Lipoma subjects affected / exposed occurrences (all) O				
Eyelid tumour subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Lipoma subjects affected / exposed occurrences (all) 0 1 Lung neoplasm subjects affected / exposed occurrences (all) 1 0 1 Lung neoplasm subjects affected / exposed occurrences (all) 1 0 0 / 2368 (0.00%) 0 / 236	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) Lipoma subjects affected / exposed occurrences (all) Lung neoplasm subjects affected / exposed occurrences (all) Plasma cell myeloma subjects affected / exposed occurrences (all) Prostate cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) Seborrhoeic keratosis subjects affected / exposed occurrences (all) Seporrhoeic keratosis subjects affected / exposed occurrences (all) Squamous cell carcinoma	occurrences (all)	0	2	
occurrences (all) 0 1 Lipoma subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Lung neoplasm subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Squamous cell carcinoma 0 / 2368 (0.00%) 1 / 2368 (0.04%)	Eyelid tumour			
Lipoma subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Lung neoplasm subjects affected / exposed occurrences (all) 1 0 0 / 2368 (0.00%) 0 /	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Lung neoplasm subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Squamous cell carcinoma 0 / 2368 (0.00%) 1 / 2368 (0.04%)	occurrences (all)	0	1	
occurrences (all) Lung neoplasm subjects affected / exposed occurrences (all) Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%)	Lipoma			
Lung neoplasm subjects affected / exposed occurrences (all) Plasma cell myeloma subjects affected / exposed occurrences (all) 1	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Squamous cell carcinoma 0 / 2368 (0.00%) 1 / 2368 (0.04%)	occurrences (all)	0	1	
subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Squamous cell carcinoma 0 / 2368 (0.00%) 1 / 2368 (0.04%)	Lung neoplasm			
Plasma cell myeloma subjects affected / exposed occurrences (all) 1 / 2368 (0.04%)	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Squamous cell carcinoma 0 1	occurrences (all)	1	0	
occurrences (all) 1 0 Prostate cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 3 / 2368 (0.00%) 5 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 3 / 2368 (0.00%) 5 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 3 / 2368 (0.00%) 5 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 3 / 2368 (0.00%)	Plasma cell myeloma			
occurrences (all) Prostate cancer subjects affected / exposed occurrences (all) Renal cancer subjects affected / exposed occurrences (all) 1	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences (all) 1 0 Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Squamous cell carcinoma 1 2368 (0.00%) 1 / 2368 (0.04%)	occurrences (all)	1	0	
occurrences (all) 1 0 Renal cancer subjects affected / exposed occurrences (all) 1 / 2368 (0.04%)	Prostate cancer			
Renal cancer subjects affected / exposed occurrences (all) Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) Squamous cell carcinoma	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences (all) 1 0 Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 1 Squamous cell carcinoma 1 1	occurrences (all)	1	0	
occurrences (all) 1 Seborrhoeic keratosis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 1 Squamous cell carcinoma	Renal cancer			
Seborrhoeic keratosis subjects affected / exposed occurrences (all) Squamous cell carcinoma	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 1 Squamous cell carcinoma 1	occurrences (all)	1	0	
occurrences (all) Squamous cell carcinoma	Seborrhoeic keratosis			
occurrences (all) 0 1 Squamous cell carcinoma	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
	occurrences (all)			
	Squamous cell carcinoma			
1 1 / 2300 (U,U4%) 1 U / 2300 (U,UU%) 1	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

Squamous cell carcinoma of skin subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)	
1 1 200 (0.00 /0) 0 / 200 (0.00 /0)	
occurrences (all) 1 0	
Thyroid adenoma subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	
occurrences (all) 0 1	
Uterine leiomyoma subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)	
occurrences (all) 1 0	
Immune system disorders Contrast media allergy subjects affected / exposed occurrences (all) O / 2368 (0.00%) 1 / 2368 (0.04%)	
Drug han area neithight	
Drug hypersensitivity subjects affected / exposed 3 / 2368 (0.13%) 0 / 2368 (0.00%)	
occurrences (all)	
Hypersensitivity	
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	
occurrences (all) 0 1	
Seasonal allergy	
subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%)	
occurrences (all) 1	
General disorders and administration site conditions Administration site phlebitis	
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%)	
occurrences (all) 0 1	
Asthenia	
subjects affected / exposed 7 / 2368 (0.30%) 4 / 2368 (0.17%)	
occurrences (all) 7 4	
Catheter site pain	
occurrences (all) 0 1	
Chest discomfort subjects affected / exposed 5 / 2368 (0.21%) 5 / 2368 (0.21%)	
occurrences (all) 5	

Chest pain subjects affected / exposed	4 / 2260 (0.170)	2 / 2260 (0 420)	
occurrences (all)	4 / 2368 (0.17%) 4	3 / 2368 (0.13%) 4	
Chills			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Complication associated with device subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Disuse syndrome subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Drug intolerance subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Fatigue subjects affected / exposed	15 / 2368 (0.63%)	11 / 2368 (0.46%)	
occurrences (all)	15	12	
Feeling abnormal subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Gait disturbance subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Hernia subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Impaired healing subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Implant site extravasation subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Influenza like illness subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	

Infusion site extravasation subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Malaise		
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)
occurrences (all)	6	4
Medical device site haematoma		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Medical device site pain		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Non-cardiac chest pain		
subjects affected / exposed	5 / 2368 (0.21%)	4 / 2368 (0.17%)
occurrences (all)	5	4
Oedema		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Oedema peripheral		
subjects affected / exposed	13 / 2368 (0.55%)	29 / 2368 (1.22%)
occurrences (all)	14	31
Pain		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Peripheral swelling		
subjects affected / exposed	5 / 2368 (0.21%)	8 / 2368 (0.34%)
occurrences (all)	5	8
Pyrexia		
subjects affected / exposed	1 / 2368 (0.04%)	11 / 2368 (0.46%)
occurrences (all)	1	12
Systemic inflammatory response syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Thirst		
subjects affected / exposed	5 / 2368 (0.21%)	0 / 2368 (0.00%)

		U	
I	I		
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Acception disconden			
Affective disorder subjects affected / exposed	1 (2262 (2.040))	0 / 2260 /0 000/	
	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Anxiety subjects affected / exposed	0 (0000 (0 400)	6 (0060 (0 050()	
	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences (all)	4	6	
Confusional state			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Delirium			
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences (all)	, ,		
occurrences (aii)	3	7	
Depressed mood			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Depression			
subjects affected / exposed	5 / 2368 (0.21%)	6 / 2368 (0.25%)	
occurrences (all)		6	
(4.17)	5	U	
Disorientation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Emotional disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
	<u> </u>	<u>-</u>	l

occurrences (all)

Insomnia		
subjects affected / exposed	9 / 2368 (0.38%)	12 / 2368 (0.51%)
occurrences (all)	10	12
Intensive care unit delirium		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Mental status changes		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	2
Organic brain syndrome		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Panic reaction		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Sleep disorder		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Reproductive system and breast		
disorders Acquired hydrocele		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Acquired phimosis subjects affected / exposed	2 / 2269 (0 090/)	1 / 2269 (0 040/)
occurrences (all)	2 / 2368 (0.08%)	1 / 2368 (0.04%)
(411)		1
Balanoposthitis		
subjects affected / exposed	8 / 2368 (0.34%)	1 / 2368 (0.04%)
occurrences (all)	10	1
Benign prostatic hyperplasia		
subjects affected / exposed	7 / 2368 (0.30%)	9 / 2368 (0.38%)
occurrences (all)	7	9
Erectile dysfunction		
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)
occurrences (all)	3	1
	i e	ı

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
		1
Gynaecomastia		
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)
occurrences (all)	4	8
Pelvic pain		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Penile oedema		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Pruritus genital		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Scrotal haematocoele		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
(6.17)	1	U
Vaginal haemorrhage		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Vulvar erosion		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Injury, poisoning and procedural complications		
Animal bite		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Ankle fracture		
subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)
occurrences (all)	5	2
A.I. 11."		
Arthropod bite subjects affected / exposed	1 / 2269 /0 049/3	2 / 2269 /0 000/ \
occurrences (all)	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (air)	1	2
Arthropod sting		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	i	

Bone contusion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Bone fissure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Chest injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Chillblains			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Clavicle fracture			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Compression fracture			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Contusion			
subjects affected / exposed	10 / 2368 (0.42%)	9 / 2368 (0.38%)	
occurrences (all)	10	10	
Craniocerebral injury			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Face injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Facial bones fracture			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Fall			
subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)	
occurrences (all)	5	3	
Fibula fracture			
subjects affected / exposed	0 / 2368 (0.00%)	4 / 2368 (0.17%)	
occurrences (all)	0	4	

Foot fracture		
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)
occurrences (all)	2	2
Forearm fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Frostbite		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Hand fracture		
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Head injury		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Heat illness		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Joint dislocation		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Joint injury		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Ligament injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Ligament sprain		
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)
occurrences (all)	4	2

Limb injury		
Limb injury subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
		J
Lower limb fracture		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Lumbar vertebral fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Meniscus injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)		1
		_
Mouth injury subjects affected / exposed		
	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Muscle rupture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Muscle strain		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Oata a ah an dual fua atuwa		
Osteochondral fracture subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
(,		1
Patella fracture		
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)
occurrences (all)	0	2
Post procedural haematoma		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Post procedural haemorrhage		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dock two weather and to word		
Post-traumatic neck syndrome subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0 / 2308 (0.00%)
		<u> </u>

Postoperative delirium subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Procedural pain subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Pseudophakic bullous keratopathy subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Radius fracture subjects affected / exposed occurrences (all)	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
Reactive gastropathy subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Rib fracture subjects affected / exposed	2 / 2368 (0.08%)	8 / 2368 (0.34%)	
occurrences (all)	2	8	
Road traffic accident subjects affected / exposed occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
		_	
Scratch subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Skin abrasion subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences (all)	4	3	
Skin injury subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Skin laceration subjects affected / exposed	5 / 2368 (0.21%)	2 / 2368 (0.08%)	
occurrences (all)	6	2 / 2308 (0.0870)	
5555 5555 (dii)			
Skull fracture			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	

Spinal column injury		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Spinal compression fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Spinal cord injury cervical		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Subcutaneous haematoma subjects affected / exposed	0 / 2260 /0 000/)	1 / 2260 (0.040()
occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (an)	0	1
Tendon injury		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Thoracic vertebral fracture		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Tooth fracture		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Tooth injury subjects affected / exposed	0 / 2260 /0 000/)	1 / 2260 (0.040()
occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (un)	0	1
Toxicity to various agents		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Upper limb fracture		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Wound		
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)
occurrences (all)	1	5
W. I. B. W.		
Wound complication subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1 / 2368 (0.04%)	1 / 2368 (0.04%)
(3)	l	1

Wound haemorrhage subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Wrist fracture			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
nvestigations			
Bleeding time prolonged			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Acinetobacter test positive			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Blood creatine increased			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Blood creatinine increased			
subjects affected / exposed	24 / 2368 (1.01%)	25 / 2368 (1.06%)	
occurrences (all)	27	26	
Blood glucose increased			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Blood potassium decreased			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Blood potassium increased			
subjects affected / exposed	11 / 2368 (0.46%)	1 / 2368 (0.04%)	
occurrences (all)	12	1	
Blood pressure decreased			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Blood pressure increased			

subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)
occurrences (all)	1	3
Blood thyroid stimulating hormone increased		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
	_	_
Blood urea increased subjects affected / exposed	0 / 2250 /0 200/)	F / 2260 (0.240()
	9 / 2368 (0.38%)	5 / 2368 (0.21%)
occurrences (all)	9	5
Blood uric acid increased		
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)
occurrences (all)	1	2
Brain natriuretic peptide increased		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
C was abit to must be in the successful		
C-reactive protein increased subjects affected / exposed	2 / 2368 (0.08%)	5 / 2368 (0.21%)
occurrences (all)	3	5
()	3	3
Candida test positive		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cardiac murmur		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Cardioactive drug level increased		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cardiovascular evaluation		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
		_
Coagulation time shortened subjects affected / exposed	0 / 2260 /0 200/	1 / 2260 /0.040/
occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Ejection fraction decreased		
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
	I	

Eosinophil count increased			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Gamma-glutamyltransferase			
increased subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
, ,	_		
Glomerular filtration rate abnormal			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Glomerular filtration rate decreased			
subjects affected / exposed	15 / 2368 (0.63%)	21 / 2368 (0.89%)	
occurrences (all)	16	22	
Glycosylated haemoglobin increased			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences (all)	3	2	
Haematocrit increased			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Unempalehin decreased			
Haemoglobin decreased subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
• •	Ĭ		
Heart rate increased			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Helicobacter test positive			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Hepatic enzyme increased			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
	i i		
International normalised ratio			
International normalised ratio increased subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
increased	1 / 2368 (0.04%) 1	4 / 2368 (0.17%) 4	
increased subjects affected / exposed			

occurrences (all)	1	0
Liver function test abnormal subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Liver function test increased subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Low density lipoprotein increased subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
N-terminal prohormone brain natriuretic peptide increased		
subjects affected / exposed occurrences (all)	2 / 2368 (0.08%)	4 / 2368 (0.17%)
occurrences (an)	2	4
Occult blood positive subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Oxygen saturation decreased subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Platelet count decreased subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Renal function test abnormal subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)
occurrences (all)	2	0
Transaminases increased subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)
occurrences (all)	0	3
Urine analysis abnormal subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Vitamin B12 decreased subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Weight decreased		

subjects affected / exposed	4 / 2368 (0.17%)	6 / 2368 (0.25%)	
occurrences (all)	4	6	
Weight increased			
subjects affected / exposed	2 / 2368 (0.08%)	10 / 2368 (0.42%)	
occurrences (all)	2	10	
Cardiac disorders Atrial fibrillation			
subjects affected / exposed	58 / 2368 (2.45%)	52 / 2368 (2.20%)	
occurrences (all)	63	55	
Cardiac failure			
subjects affected / exposed	76 / 2368 (3.21%)	130 / 2368 (5.49%)	
occurrences (all)	90	154	
Acute coronary syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Angina nagtaria			
Angina pectoris subjects affected / exposed	8 / 2368 (0.34%)	17 / 2368 (0.72%)	
occurrences (all)	10	22	
,		22	
Acute myocardial infarction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Angina unstable			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Arrhythmia subjects affected / exposed	1 / 2269 /0 049/	2 / 2269 /0 000/ \	
occurrences (all)	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (un)	1	2	
Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Atrial flutter			
subjects affected / exposed	10 / 2368 (0.42%)	9 / 2368 (0.38%)	
occurrences (all)	10	9	
Atrial tachycardia subjects affected / exposed	2 / 2260 / 2 666/	6 / 2260 / 255/	
-	2 / 2368 (0.08%)	6 / 2368 (0.25%)	
occurrences (all)	6	6	

Atrial thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Abria, antria, da u bla alc			
Atrioventricular block subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)		1	
occurrences (an)	1	0	
Atrioventricular block complete			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Atrioventricular block first degree			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
V- /			
Bradyarrhythmia			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Bradycardia			
subjects affected / exposed	3 / 2368 (0.13%)	7 / 2368 (0.30%)	
occurrences (all)	3	7	
		,	
Bundle branch block left			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Cardiac aneurysm			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
	_		
Bundle branch block right			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Cardiac asthma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Cardiac failure acute subjects affected / exposed	2 / 2260 /0 000/ \	4 / 2200 /0 170/	
	2 / 2368 (0.08%)	4 / 2368 (0.17%)	
occurrences (all)	2	5	
Cardiac failure chronic			
subjects affected / exposed	4 / 2368 (0.17%)	10 / 2368 (0.42%)	
occurrences (all)	5	12	

Cardiac failure congestive			
subjects affected / exposed	15 / 2368 (0.63%)	12 / 2368 (0.51%)	
occurrences (all)	16	14	
Cardiac ventricular thrombosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Cardiomegaly			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Cardiomyopathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Chronotropic incompetence			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Canadan antoni dia aa			
Coronary artery disease subjects affected / exposed	0 / 2368 (0.00%)	5 / 2368 (0.21%)	
occurrences (all)	0 / 2300 (0.00 /0)	5	
Coronary artery stenosis subjects affected / exposed	1 (2250 (0.040))	2 / 2262 / 2 226/)	
occurrences (all)	1 / 2368 (0.04%)		
occurrences (aii)	1	2	
Extrasystoles			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Intracardiac thrombus			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Left ventricular dysfunction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Left ventricular failure			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Left ventricular hypertrophy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	

Mitral valve disease			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Mitral valve incompetence			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Myocardial infarction			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Myocardial ischaemia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Palpitations			
subjects affected / exposed	4 / 2368 (0.17%)	8 / 2368 (0.34%)	
occurrences (all)	4 / 2308 (0.17 70)	10	
Pericardial effusion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Pericardial haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Sinus arrest			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Sinus bradycardia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Sinus node dysfunction			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Sinus tachycardia			
Sinus tachycardia subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0 000/)	
		2 / 2368 (0.08%)	
occurrences (all)	0	2	
Tachycardia			
Tachycardia subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	

Tachycardia paroxysmal subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Tricuspid valve incompetence subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Ventricular arrhythmia subjects affected / exposed occurrences (all)	2 / 2368 (0.08%)	1 / 2368 (0.04%) 1	
Ventricular extrasystoles subjects affected / exposed occurrences (all)	3 / 2368 (0.13%) 3	4 / 2368 (0.17%) 4	
Ventricular fibrillation subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	2 / 2368 (0.08%) 2	
Ventricular tachyarrhythmia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Ventricular tachycardia subjects affected / exposed occurrences (all)	12 / 2368 (0.51%) 19	18 / 2368 (0.76%) 22	
Blood and lymphatic system disorders Abdominal lymphadenopathy subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Anaemia subjects affected / exposed occurrences (all)	10 / 2368 (0.42%) 10	13 / 2368 (0.55%) 13	
Blood loss anaemia subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Hypochromic anaemia subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Iron deficiency anaemia subjects affected / exposed	4 / 2368 (0.17%)	10 / 2368 (0.42%)	

occurrences (all)	4	10	
Leukocytosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Lymphadenopathy subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Microcytic anaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Nephrogenic anaemia subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	
occurrences (all)	3	3	
Normochromic normocytic anaemia subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Normocytic anaemia subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Polycythaemia subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Splenomegaly subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Thrombocytopenia subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1 / 2300 (0.0470)	2	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	

Asthma			
subjects affected / exposed	4 / 2368 (0.17%)	2 / 2368 (0.08%)	
occurrences (all)	4	3	
Bronchial disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
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Bronchitis chronic			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Chronic obstructive pulmonary disease			
subjects affected / exposed	6 / 2368 (0.25%)	10 / 2368 (0.42%)	
occurrences (all)	7	12	
• •	<u> </u>		
Cough			
subjects affected / exposed	14 / 2368 (0.59%)	18 / 2368 (0.76%)	
occurrences (all)	16	19	
Dysphonia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Durana			
Dyspnoea subjects affected / exposed	20 / 2269 (0.940/)	23 / 2260 /1 200/ \	
occurrences (all)	20 / 2368 (0.84%)		
occanionate (un)	22	35	
Dyspnoea exertional			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Dyspnoea paroxysmal nocturnal			
subjects affected / exposed	0 / 2368 (0.00%)	4 / 2368 (0.17%)	
occurrences (all)	0	4	
Emphysema subjects affected / exposed	2 / 2252 / 2 5 5 5 5 5 5	0 / 2252 /2 5333	
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Epistaxis			
subjects affected / exposed	8 / 2368 (0.34%)	8 / 2368 (0.34%)	
occurrences (all)	9	8	
Haemoptysis			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences (all)	1	4 / 2300 (0.17 /0)	
		 	

Hiccups			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Nasal congestion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Nasal polyps			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Obstructive airways disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Oropharyngeal pain			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Pleural effusion			
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)	
occurrences (all)	2	6	
Pleural fibrosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Pleural thickening			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Pleurisy			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Pneumonia aspiration			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Pneumothorax			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	3	0	
Productive cough			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	

Pulmonary calcification			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Pulmonary congestion			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences (all)	1	4	
Pulmonary embolism			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Pulmonary hypertension			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Pulmonary mass			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Pulmonary oedema			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Respiratory disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Respiratory failure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Rhinitis allergic			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Rhinorrhoea			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Sleep apnoea syndrome			
subjects affected / exposed	3 / 2368 (0.13%)	3 / 2368 (0.13%)	
occurrences (all)	3	3	
Tachypnoea			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	

Throat irritation subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Upper respiratory tract inflammation subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 2	6 / 2368 (0.25%) 7	
Wheezing subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Nervous system disorders Ageusia subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Aphasia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Ataxia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Autonomic neuropathy subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Balance disorder subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Brain oedema subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Carotid arteriosclerosis subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Carotid artery disease subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	
Carotid artery occlusion subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0	
Carotid artery stenosis subjects affected / exposed	1 / 2260 /0 040/	1 / 2269 /0 049/	
occurrences (all)	1 / 2368 (0.04%)	1 / 2368 (0.04%) 1	
Cerebral atrophy			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Cerebrovascular accident subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Canalananaanilan diaandan			
Cerebrovascular disorder subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
- (- /			
Cervicobrachial syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Cognitive disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Dementia			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences (all)	3	2	
		_	
Dementia Alzheimer's type			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Diplegia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Diabetic neuropathy			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Diehushanaa in attautia			
Disturbance in attention subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
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Dizziness			
subjects affected / exposed	44 / 2368 (1.86%)	26 / 2368 (1.10%)	

occurrences (all)	49	28	
Dizziness postural subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Dysdiadochokinesis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Dysgeusia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Facial paralysis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
llee de che			
Headache subjects affected / exposed	10 / 2260 (0 420/)	0 / 2260 /0 240/)	
	10 / 2368 (0.42%)	8 / 2368 (0.34%)	
occurrences (all)	10	8	
Hypoaesthesia			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Hypotonia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Ischaemic stroke			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Lacunar infarction			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	
Leukoencephalopathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Langue de compaña de c			
Loss of consciousness subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)		3 / 2368 (0.13%)	
(2)	1	3	
Memory impairment			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	

occurrences (all)	1	1	
Migraine			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Myoclonus			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Neuropathy peripheral			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences (all)	0	3	
Nystagmus			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Peripheral nerve paresis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Peroneal nerve palsy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Polyneuropathy			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Post herpetic neuralgia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Presyncope			
subjects affected / exposed	5 / 2368 (0.21%)	1 / 2368 (0.04%)	
occurrences (all)	6	1	
Psychomotor hyperactivity			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Radiculopathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0	
Reduced facial expression			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Retrograde amnesia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Sciatica			
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)	
occurrences (all)	2	6	
Somnolence			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Syncope			
subjects affected / exposed	6 / 2368 (0.25%)	9 / 2368 (0.38%)	
occurrences (all)	6	10	
Taste disorder			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Transient ischaemic attack			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Tremor			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Uraemic encephalopathy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Visual field defect			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Blepharitis			

subjects affected / exposed occurrences (all) 7 15 16 17 18 18 18 19 19 19 19 19 19 19 19 19 19 19 19 19	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) 7 15 20 project affected / exposed occurrences (all) 80 projects affected / exposed occurrences (all) 81 projects affected / exposed occurrences (all) 81 projects affected / exposed occurrences (all) 81 projects affected / exposed occur	occurrences (all)	0	1	
2	Cataract			
Conjunctival haemorrhage subjects affected / exposed occurrences (all) Conjunctivitis allergic subjects affected / exposed occurrences (all) Corpora verticillata subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis acquired subjects affected / exposed occurrences (all) Corpostenosis (subjects affected / exposed	6 / 2368 (0.25%)	14 / 2368 (0.59%)	
subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 conjunctivitis allergic subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 0 courrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 courrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 courrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 courrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 2 / 2368 (0.04%) 2 / 2368 (0.04%) 0 courrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 2 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 2 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 2 / 2368 (0.00%) 1 / 2368 (0.00%)	occurrences (all)	7	15	
0 3 3 3 3 3 3 3 3 3	Conjunctival haemorrhage			
Conjunctivitis allergic subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata subjects affected / exposed occurrences (all) Cornea verticillata occurrences (all) Docurrences (all) Cornea verticillata occurrences (all) Docurrences (all) Cornea verticillata occurrences (all) Docurrences		0 / 2368 (0.00%)	2 / 2368 (0.08%)	
subjects affected / exposed occurrences (all) O	occurrences (all)	0	3	
Occurrences (all)	Conjunctivitis allergic			
Cornea verticillata subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Correspondences (all) 0 / 1 Correspondences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Correspondences (all) 0 / 1 Correspondences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Correspondences (all) 1 / 2368 (0.04%) 2 / 2368 (0.08%) 0 1 Correspondences (all) 1 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Correspondences (all) 0 / 1 Correspondences (all) 0 / 1 Correspondences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Correspondences (all) 0 / 1 Correspondences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 236	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis acquired subjects affected / exposed occurrences (all) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis acquired acoos (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis affected (acoos) Oacryostenosis (acoos) Oacryostenosis (acoos) Oacryostenosis (acoos) Oacryostenosis (acoos	occurrences (all)	0	1	
occurrences (all) occurrences (all)	Cornea verticillata			
Dacryostenosis acquired subjects affected / exposed occurrences (all) Diabetic retinopathy subjects affected / exposed occurrences (all) Dry eye subjects affected / exposed o	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Diabetic retinopathy subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 2 / 2368 (0.08%) 1 / 2368 (0.08%) 2 / 2368 (0.08%) 2 / 2368 (0.08%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Eye haemorrhage subjects affected / exposed occurrences (all) 0 1 Eye irritation subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%)	occurrences (all)	0	1	
occurrences (all) 0 1 Diabetic retinopathy subjects affected / exposed occurrences (all) 1 2 Ory eye subjects affected / exposed occurrences (all) 0 1 2 Ory eye subjects affected / exposed occurrences (all) 0 1 2 Ory eye subjects affected / exposed occurrences (all) 0 1 Eye haemorrhage subjects affected / exposed occurrences (all) 0 1 Eye irritation subjects affected / exposed occurrences (all) 1 Ory eye 1 / 2368 (0.00%) 0 1 / 2368 (0.04%) 0 1 Eyelid bleeding subjects affected / exposed occurrences (all) 0 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%)	Dacryostenosis acquired			
Diabetic retinopathy subjects affected / exposed occurrences (all) 1	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 2 / 2368 (0.08%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.04%) 0 ccurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 ccurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 ccurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 2 / 2368 (0.00%) 1 / 2368 (0.00%)	occurrences (all)	0	1	
1	Diabetic retinopathy			
Ory eye subjects affected / exposed occurrences (all) 0 1 1 2368 (0.04%) 0 1 / 2368 (0.04%) 0 1 / 2368 (0.04%) 0 1 / 2368 (0.04%) 0 1 / 2368 (0.04%) 0 1 / 2368 (0.04%) 0 1 / 2368 (0.04%) 0 1 / 2368 (0.00%) 0 1 / 2368 (0.00%) 0 1 / 2368 (0.00%) 0 1 / 2368 (0.00%) 0 1 / 2368 (0.00%) 0 1 / 2368 (0.00%) 0 1 / 2368 (0.04	subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
subjects affected / exposed occurrences (all) occurrences (all)	occurrences (all)	1	2	
occurrences (all) 0 1 Eye haemorrhage subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences (all) 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences (all)	Dry eye			
Eye haemorrhage subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 1 Eye irritation subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed	occurrences (all)	0	1	
occurrences (all) 0 1 Eye irritation subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 2 / 2368 (0.08%) 1 / 2368 (0.04%)	Eye haemorrhage			
Eye irritation subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.08%) 1 / 2368 (0.04%) 0 / 2368 (0.08%) 1 / 2368 (0.04%) 0 / 2368 (0.08%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 1 / 2368 (subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed	occurrences (all)	0	1	
occurrences (all) 1 0 Eyelid bleeding subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) 1 Glaucoma subjects affected / exposed occurrences (all) 2 / 2368 (0.08%) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 1 / 2368 (0.04%)	Eye irritation			
Eyelid bleeding subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) 0 ccurrences (all) 0 1 Glaucoma subjects affected / exposed 2 / 2368 (0.08%) 1 / 2368 (0.04%) 0 ccurrences (all) 2 1	subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
subjects affected / exposed 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 1 Glaucoma subjects affected / exposed occurrences (all) 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences (all) 2 1	occurrences (all)	1	0	
occurrences (all) 0 1 Glaucoma subjects affected / exposed occurrences (all) 2 / 2368 (0.08%) 1 / 2368 (0.04%) 2 1	Eyelid bleeding			
Glaucoma subjects affected / exposed 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences (all) 2 1		0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences (all) 2 1	occurrences (all)	0	1	
occurrences (all) 2 1	Glaucoma			
	subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
lypermetropia	occurrences (all)	2	1	
	Hypermetropia			

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Macular fibrosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Ocular hyperaemia			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Retinal artery occlusion			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Photopsia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Retinal detachment			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences (all)	0	3	
Retinal vein occlusion			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Retinal vascular thrombosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Retinopathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Ulcerative keratitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Scintillating scotoma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Vision blurred			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Vigual impointment			
Visual impairment subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
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Vitreous degeneration		. ,	
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Deafness neurosensory			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Ear canal stenosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
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Ear discomfort			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Ear haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Eustachian tube dysfunction			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Hypoacusis subjects affected / exposed	0 / 2250 / 2 2251	1 / 2260 / 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Tinnitus			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Tympanic membrane perforation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
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Vertigo			
subjects affected / exposed	3 / 2368 (0.13%)	7 / 2368 (0.30%)	
occurrences (all)	3	7	
Vertigo positional			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	7 / 2368 (0.30%)	3 / 2368 (0.13%)	
occurrences (all)	7	3	
Abdominal distension			
subjects affected / exposed	1 / 2368 (0.04%)	5 / 2368 (0.21%)	
occurrences (all)	1	5	
Abdominal hernia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Abdominal pain			
subjects affected / exposed	6 / 2368 (0.25%)	9 / 2368 (0.38%)	
occurrences (all)	6	9	
Abdominal pain lower			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Abdominal pain upper			
subjects affected / exposed	7 / 2368 (0.30%)	4 / 2368 (0.17%)	
occurrences (all)	7	4	
Anal fistula			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Anal fissure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Anal pruritus			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Ascites			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	

occurrences (all)	2	1	
Aptyalism			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Chronic gastritis			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences (all)	2	3	
Coeliac artery stenosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Colitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0 / 2308 (0.00 %)	1	
- 35a 5555 (all)			
Colitis ulcerative			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	8 / 2368 (0.34%)	27 / 2368 (1.14%)	
occurrences (all)	8	28	
Defaecation urgency			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Dental caries			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences (all)	3	2	
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Diarrhoea			
subjects affected / exposed	25 / 2368 (1.06%)	32 / 2368 (1.35%)	
occurrences (all)	27	32	
Diverticulum intestinal			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Diverticulum			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Dry mouth			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0 00%)	
carearda / capobea	1 / 2300 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0	
Duodenal ulcer			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Dysphagia			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Dyspepsia			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Enteritis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Enterocolitis			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Erosive oesophagitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Faces discolaring d			
Faeces discoloured subjects affected / exposed	0 / 2269 (0 000/)	1 / 2269 (0 049/)	
	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Faeces hard			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Flatulence			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	
Food poisoning			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Gastric disorder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Gastric polyps			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences (all)	0	1	
Gastric ulcer			
subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Gastritis			
subjects affected / exposed	6 / 2368 (0.25%)	5 / 2368 (0.21%)	
occurrences (all)	7	5	
Gastritis erosive			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Gastrointestinal angiodysplasia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Gastrointestinal haemorrhage			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2 / 2308 (0.0870)	1 / 2508 (0.04%)	
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Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Gingival pain			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Gingival swelling			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Glossitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Haematochezia			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Hiatus hernia			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Ileus paralytic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Inguinal hernia			
subjects affected / exposed	4 / 2368 (0.17%)	2 / 2368 (0.08%)	
occurrences (all)	4	2	
Irritable bowel syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
		-	
Large intestinal stenosis subjects affected / exposed	1 (2252 (2.242))		
	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Large intestinal ulcer			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Large intestine polyp			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	9 / 2368 (0.38%)	8 / 2368 (0.34%)	
occurrences (all)	9	9	
Lip swelling			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Oesophagitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
December 41 1			
Pancreatic disorder subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
and an arrangement of the second	1 / 2300 (0.04%)	0 / 2300 (0.00%)	

occurrences (all)	1	0	
Oral pain			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Pancreatitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Periodontal disease			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Peritoneal haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Portal hypertensive gastropathy subjects affected / exposed	1 (2252 (2.242)	0 (0000 (0 000)	
	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Rectal haemorrhage			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences (all)	0	3	
Toothache			
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences (all)	4	4	
Umbilical hernia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Mariana annulis essal			
Varices oesophageal subjects affected / exposed	2 / 2360 /0 000/	1 / 2369 (0 040/)	
	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	3	1	
Vomiting			
subjects affected / exposed	6 / 2368 (0.25%)	5 / 2368 (0.21%)	

	I		l
Hepatobiliary disorders			
Alcoholic liver disease			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Cholelithiasis subjects affected / exposed	E / 2252 /2 249/	0 / 0000 /0 /00/	
	5 / 2368 (0.21%)	3 / 2368 (0.13%)	
occurrences (all)	5	3	
Cryptogenic cirrhosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Hepatic cirrhosis subjects affected / exposed	1 / 2250 /0 040/)	4 / 2250 /0 040/)	
	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Hepatic congestion			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Hepatic cyst subjects affected / exposed	1 / 2260 /0 040/)	1 / 2260 (0.040/)	
	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Hepatic failure			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	2	
Hanakia Gurakian aharanya			
Hepatic function abnormal subjects affected / exposed	2 / 2269 (0 090/)	2 / 2269 /0 120/ \	
occurrences (all)	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences (aii)	2	3	
Hepatic steatosis			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	
Hanatitic			
Hepatitis subjects affected / exposed	0 / 2260 (0 000/)	1 / 2260 (0.040/.)	
occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Hepatorenal failure			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	

occurrences (all)

Liver disorder			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	2	
Liver injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Portal hypertension			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders Renal impairment			
subjects affected / exposed	63 / 2368 (2.66%)	56 / 2368 (2.36%)	
occurrences (all)	67	60	
Azotaemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Acute kidney injury subjects affected / exposed	26 / 2368 (1.10%)	26 / 2368 (1.10%)	
occurrences (all)	28	29	
		23	
Calculus urinary subjects affected / exposed	1 (2250 (2.040))		
	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Cystitis haemorrhagic			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Chronic kidney disease			
subjects affected / exposed	15 / 2368 (0.63%)	18 / 2368 (0.76%)	
occurrences (all)	15	23	
Diabetic nephropathy			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Dysuria			
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)	
occurrences (all)	6	4	
Chappania			
Glycosuria subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
1	1 / 2300 (0.0470)	0 / 2300 (0.0070)	

occurrences (all)	1	0	
Haematuria			
subjects affected / exposed	5 / 2368 (0.21%)	10 / 2368 (0.42%)	
occurrences (all)	5	11	
Hypertonic bladder			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Incontinence			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Microalbuminuria			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Micturition disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Micturition urgency			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Nephrolithiasis			
subjects affected / exposed	4 / 2368 (0.17%)	2 / 2368 (0.08%)	
occurrences (all)	4	2	
Nephropathy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Nephropathy toxic			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Nocturia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Pollakiuria			
subjects affected / exposed	6 / 2368 (0.25%)	3 / 2368 (0.13%)	
occurrences (all)	6	3	
Polyuria			
subjects affected / exposed		1	

occurrences (all)	1	1	
Prerenal failure			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Proteinuria			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Renal atrophy			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Renal cyst			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences (all)	3	2	
Renal disorder			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
D 16.1			
Renal failure			
subjects affected / exposed	37 / 2368 (1.56%)	32 / 2368 (1.35%)	
occurrences (all)	39	37	
Renal injury			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Renal mass			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Urethral atrophy			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Urethral caruncle			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Urethral obstruction			
subjects affected / exposed	0 / 2269 /0 009/)	1 / 2269 (0.049()	
Sabjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences (all)	0	1	
Urethritis noninfective			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Urinary incontinence			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	3	0	
Urinary retention			
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences (all)	3	4	
Urinary tract inflammation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Product issues			
Device battery issue			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Device malfunction			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Skin and subcutaneous tissue disorders			
Actinic keratosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Alopecia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Asteatosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Blister			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Decubitus ulcer			
subjects affected / exposed	0 / 2368 (0.00%)	4 / 2368 (0.17%)	
occurrences (all)	0	4	
			ı l

Dermatitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Dermatitis allergic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Dermatitis contact			
subjects affected / exposed	3 / 2368 (0.13%)	2 / 2368 (0.08%)	
occurrences (all)	3	2	
Dermatitis exfoliative generalised			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Diabetic foot			
subjects affected / exposed	6 / 2368 (0.25%)	1 / 2368 (0.04%)	
occurrences (all)			
occurrences (all)	6	1	
Drug eruption			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Dry skin			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Ecchymosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Eczema			
subjects affected / exposed	9 / 2368 (0.38%)	4 / 2368 (0.17%)	
occurrences (all)	10	4	
Eczema asteatotic			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	3	
Erythema			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences (all)	0	3	
Erythema multiforme			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0		
		-	

Haemorrhage subcutaneous			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences (all)	2	3	
Henoch-Schonlein purpura			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Hyperhidrosis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
To average and the			
Ingrowing nail subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
occurrences (un)		U	
Lichenoid keratosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Lichen sclerosus			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Onychomodonia			
Onychomadesis subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0 / 2300 (0.00 %)	1	
occan chocc (an)		1	
Peau d'orange			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Petechiae			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Photosensitivity reaction			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1 / 2308 (0.04%)	1 1 2 2 3 3 (0.04 70)	
. ,		_	
Pruritus			
subjects affected / exposed	9 / 2368 (0.38%)	9 / 2368 (0.38%)	
occurrences (all)	10	10	
Rash			
subjects affected / exposed	14 / 2368 (0.59%)	11 / 2368 (0.46%)	
occurrences (all)	14	12	

Pruritus generalised		[[
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Pach generalized			
Rash generalised subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)			
occurrences (an)	1	0	
Rash erythematous			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	3	0	
Rash pruritic			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
()			
Sebaceous hyperplasia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Skin erosion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)			
- 333 3 3 (dii)	1	0	
Skin irritation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Skin lesion			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Chin macc			
Skin mass subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)			
occurrences (an)	0	1	
Skin ulcer			
subjects affected / exposed	5 / 2368 (0.21%)	8 / 2368 (0.34%)	
occurrences (all)	6	8	
Swelling face			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	

Subjects affected / exposed occurrences (all)	Urticaria			
Musculoskeletal and connective tissue disorders	subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
Arthralgia subjects affected / exposed occurrences (alli) Arthritis subjects affected / exposed occurrences (alli) Arthropathy subjects affected / exposed occurrences (alli) Back pain subjects affected / exposed occurrences (alli) Back pain subjects affected / exposed occurrences (alli) Bone pain subjects affected / exposed occurrences (alli) Bursitis subjects affected / exposed occurrences (alli) Bursitis subjects affected / exposed occurrences (alli) Bursitis subjects affected / exposed occurrences (alli) Condrocalcinosis pyrophosphate subjects affected / exposed occurrences (alli) Costochondritis subjects affected / exposed occurrences (alli) Dupuytren's contracture subjects affected / exposed occurrences (alli) Dupuytren's contracture subjects affected / exposed occurrences (alli) Exostosis subjects affected / exposed occurrences (alli) I 1 Exostosis subjects affected / exposed occurrences (alli) I 2368 (0.04%)	occurrences (all)	2	3	
Arthralgia subjects affected / exposed occurrences (all) 8 / 2368 (0.34%) 16 Arthritis subjects affected / exposed occurrences (all) 2 / 2368 (0.08%) 1 / 2368 (0.04%) occurrences (all) 2 1 Arthropathy subjects affected / exposed occurrences (all) 1 1 Back pain subjects affected / exposed occurrences (all) 1 1 Back pain subjects affected / exposed occurrences (all) 19 / 2368 (0.08%) 27 / 2368 (1.14%) 29 Bone pain subjects affected / exposed occurrences (all) 2 / 2368 (0.08%) 0 / 2368 (0.00%) occurrences (all) 2 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences (all) 1 1 Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) 1 1 Costochondritis subjects affected / exposed occurrences (all) 1 1 Costochondritis subjects affected / exposed occurrences (all) 1 1 Dupuytren's contracture subjects affected / exposed occurrences (all) 1 0 Exostosis subjects affected / exposed occurrences (all) 1 0 Exostosis subjects affected / exposed occurrences (all) 1 0 Exostosis subjects affected / exposed occurrences (all) 1 1 Flank pain				
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subjects affected / exposed occurrences (all) Arthropathy subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Bone pain subjects affected / exposed occurrences (all) Bursitis subjects affected / exposed occurrences (all) Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) Costochondritis subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) Exostosis subjects affected / exposed occurrences (all) 1	occurrences (all)	8	16	
occurrences (all) 2 1 Arthropathy subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Back pain subjects affected / exposed occurrences (all) 19 / 2368 (0.80%) 27 / 2368 (1.14%) Bone pain subjects affected / exposed occurrences (all) 2 / 2368 (0.08%) 0 / 2368 (0.00%) Bursitis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Costochondritis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Flank pain 1 / 2368 (0.04%) 1 / 2368 (0.04%)	Arthritis			
occurrences (all) 2 1 Arthropathy subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Back pain subjects affected / exposed occurrences (all) 19 / 2368 (0.80%) 27 / 2368 (1.14%) Bone pain subjects affected / exposed occurrences (all) 2 / 2368 (0.08%) 0 / 2368 (0.00%) Bursitis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Ocurrences (all) 1 1 Dupuytren's contracture subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 0 / 2368 (0.00%) Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Flank pain 1 1 1	subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Bone pain subjects affected / exposed occurrences (all) Bursitis subjects affected / exposed occurrences (all) Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) Costochondritis subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) Exostosis subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all) Dipuptren's contracture subjects affected / exposed occurrences (all	occurrences (all)			
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Description		1 / 2368 (0.04%)	1 / 2368 (0 04%)	
Back pain subjects affected / exposed occurrences (all) 19 / 2368 (0.80%) 27 / 2368 (1.14%) 29 Bone pain subjects affected / exposed occurrences (all) 2 0 Bursitis subjects affected / exposed occurrences (all) 1 1 1 Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) 1 1 1 Costochondritis subjects affected / exposed occurrences (all) 1 1 1 Costochondritis subjects affected / exposed occurrences (all) 1 1 1 Costochondritis subjects affected / exposed occurrences (all) 0 1 1 Dupuytren's contracture subjects affected / exposed occurrences (all) 1 0 1 Exostosis subjects affected / exposed occurrences (all) 1 0 Exostosis subjects affected / exposed occurrences (all) 1 1 0 Flank pain				
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Bone pain subjects affected / exposed occurrences (all) Bursitis subjects affected / exposed occurrences (all) Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) Costochondritis subjects affected / exposed occurrences (all) Costochondritis subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%)		19 / 2368 (0.80%)	27 / 2368 (1.14%)	
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occurrences (all) 2 0 Bursitis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Occurrences (all) 1 1 Costochondritis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Occurrences (all) 1 0 1 Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Occurrences (all) 1 0 Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Flank pain 1 1 1	Bone pain			
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Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all) Costochondritis subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) Exostosis subjects affected / exposed occurrences (all) Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%)	subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Costochondritis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Flank pain 1 / 2368 (0.04%) 1 / 2368 (0.04%)	occurrences (all)	1	1	
occurrences (all) 1 1 Costochondritis subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) occurrences (all) 0 1 Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences (all) 1 0 Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences (all) 1 1	Chondrocalcinosis pyrophosphate			
Costochondritis subjects affected / exposed occurrences (all) Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.00%) 1 / 2368 (0.04%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 0 / 2368 (0.00%) 0 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%) 1 / 2368 (0.00%)	subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
subjects affected / exposed occurrences (all) 0 / 2368 (0.00%) 1 / 2368 (0.04%) Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Flank pain 1 1	occurrences (all)	1	1	
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occurrences (all) 0 1 Dupuytren's contracture subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences (all) 1 0 Exostosis subjects affected / exposed occurrences (all) 1 / 2368 (0.04%) 1 / 2368 (0.04%) Flank pain 1 1	subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences (all) 1 0 Exostosis 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences (all) 1 1 Flank pain 1 1	occurrences (all)	0	1	
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%) occurrences (all) 1 0 Exostosis 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences (all) 1 1 Flank pain 1 1	Dupuytren's contracture			
occurrences (all) 1 0 Exostosis subjects affected / exposed 1 / 2368 (0.04%) 1 / 2368 (0.04%) occurrences (all) 1 1 Flank pain		1 / 2368 (0.04%)	0 / 2368 (0.00%)	
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occurrences (all) 1 Flank pain		1 / 2368 (0.04%)	1 / 2368 (0 04%)	
	Flank pain			
subjects affected / exposed 1 / 2368 (0.04%) 0 / 2368 (0.00%)	·	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0	
Foot deformity			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Gouty arthritis			
subjects affected / exposed	3 / 2368 (0.13%)	4 / 2368 (0.17%)	
occurrences (all)	3	4	
Groin pain			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Intervertebral disc protrusion			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences (all)	0	3	
Joint swelling			
subjects affected / exposed	2 / 2269 (0.099/)	2 / 2269 /0 099/)	
	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Lumbar spinal stenosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Muscle spasms			
subjects affected / exposed	6 / 2368 (0.25%)	4 / 2368 (0.17%)	
occurrences (all)	6	4	
Muscle tightness			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Muscular weakness			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Museulagkalatal abaat == i=			
Musculoskeletal chest pain subjects affected / exposed	7 / 2269 (0.200/)	2 / 2260 /0 120/ \	
	7 / 2368 (0.30%)	3 / 2368 (0.13%)	
occurrences (all)	8	5	
Musculoskeletal pain			
subjects affected / exposed	6 / 2368 (0.25%)	3 / 2368 (0.13%)	
occurrences (all)	6	3	
Musculoskeletal stiffness			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	

occurrences (all)	1	1	
Myalgia			
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)	
occurrences (all)	2	4	
Neck pain			
subjects affected / exposed	4 / 2368 (0.17%)	3 / 2368 (0.13%)	
occurrences (all)	5	3	
Osteitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	10 / 2368 (0.42%)	2 / 2368 (0.08%)	
occurrences (all)	10	2	
Osteochondrosis			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Osteopenia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Osteoporosis			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	3	0	
Osteosclerosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Pain in extremity			
subjects affected / exposed	12 / 2368 (0.51%)	15 / 2368 (0.63%)	
occurrences (all)	12	16	
Pain in jaw			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Periarthritis			
subjects affected / exposed	2 / 2368 (0.08%)	3 / 2368 (0.13%)	
occurrences (all)	2	3	
Periostitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	

occurrences (all)	1	0	
Pseudarthrosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Rheumatoid arthritis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Rotator cuff syndrome			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Scleroderma			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Scoliosis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Spinal deformity			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Spinal osteoarthritis			
subjects affected / exposed	4 / 2368 (0.17%)	1 / 2368 (0.04%)	
occurrences (all)	4	1	
Spinal pain			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Spinal stenosis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Trigger finger			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Vertebral osteophyte			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
ndocrine disorders			

Adrenal insufficiency			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	О	1	
Diabetes insipidus			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Hyperparathyroidism			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Hyperthyroidism			
subjects affected / exposed	5 / 2368 (0.21%)	5 / 2368 (0.21%)	
occurrences (all)	5	5	
Hypoparathyroidism	0 / 00 - 2 / 2		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Hypothyroidism			
subjects affected / exposed	9 / 2368 (0.38%)	7 / 2368 (0.30%)	
occurrences (all)	9	7	
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed	5 / 2368 (0.21%)	7 / 2368 (0.30%)	
occurrences (all)			
occurrences (un)	6	7	
Dehydration			
subjects affected / exposed	25 / 2368 (1.06%)	21 / 2368 (0.89%)	
occurrences (all)	25	23	
Diabetes mellitus			
subjects affected / exposed	23 / 2368 (0.97%)	40 / 2368 (1.69%)	
occurrences (all)	23	40	
District and the second of the			
Diabetes mellitus inadequate control subjects affected / exposed	2 / 2260 /0 000/)	2 / 2262 / 2 2263	
	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Diabetic metabolic decompensation			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Dualinida ami-			
Dyslipidaemia subjects affected / exposed	2 / 2269 (0.120/)	1 / 2260 /0 040/ \	
Sasjeets affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	

occurrences (all)	3	1	
Electrolyte imbalance			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Fluid overload			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Fluid retention			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Folate deficiency			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Channel tolores and the same to			
Glucose tolerance impaired subjects affected / exposed	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (all)	3 / 2368 (0.13%)	1 / 2368 (0.04%)	
occurrences (un)			
Gout			
subjects affected / exposed	15 / 2368 (0.63%)	' '	
occurrences (all)	16	21	
Hypercalcaemia			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Hypercholesterolaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Hyperglycaemia			
subjects affected / exposed	8 / 2368 (0.34%)	5 / 2368 (0.21%)	
occurrences (all)	8	5	
Hyporkalaomia			
Hyperkalaemia subjects affected / exposed	30 / 2368 (1.27%)	35 / 2368 (1.48%)	
occurrences (all)	34	39	
Hyperlipidaemia			
subjects affected / exposed	1 / 2368 (0.04%)	5 / 2368 (0.21%)	
occurrences (all)	1	5	
Hypernatraemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	

occurrences (all)	0	1	
Hyperphosphataemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Hyperuricaemia			
subjects affected / exposed	8 / 2368 (0.34%)	18 / 2368 (0.76%)	
occurrences (all)	8	19	
Hypervolaemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Hypoalbuminaemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)			
occurrences (air)	0	1	
Hypocalcaemia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Hypoglycaemia			
subjects affected / exposed	13 / 2368 (0.55%)	24 / 2368 (1.01%)	
occurrences (all)	17	27	
Hypokalaemia			
subjects affected / exposed	16 / 2368 (0.68%)	19 / 2368 (0.80%)	
occurrences (all)	18	23	
Hypomagnosaamia			
Hypomagnesaemia subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0 / 2308 (0.00%)	2 / 2308 (0.08%)	
Hyponatraemia subjects affected / exposed	4 / 2250 /0 170/	2 / 2260 /0 422/	
	4 / 2368 (0.17%)	3 / 2368 (0.13%)	
occurrences (all)	4	3	
Hypophosphataemia			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Hypovolaemia			

occurrences (all)	34	22	
Iron deficiency subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Magnesium deficiency subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Metabolic acidosis subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Polydipsia subjects affected / exposed occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
	0	1	
Postprandial hypoglycaemia subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Type 2 diabetes mellitus subjects affected / exposed	36 / 2368 (1.52%)	48 / 2368 (2.03%)	
occurrences (all)	36	48	
Vitamin B12 deficiency subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Vitamin D deficiency subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Infections and infestations Nasopharyngitis subjects affected / exposed	63 / 2368 (2.66%)	76 / 2368 (3.21%)	
occurrences (all)	84	100	
Abdominal sepsis subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Abscess limb subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Acarodermatitis			

subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Acute sinusitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Arthritis infective			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Appendicitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Atypical pneumonia			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Bacteraemia			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Bacterial infection			
subjects affected / exposed	0 / 2368 (0.00%)	3 / 2368 (0.13%)	
occurrences (all)	0	3	
Balanitis candida			
subjects affected / exposed	3 / 2368 (0.13%)	0 / 2368 (0.00%)	
occurrences (all)	7	0	
Bronchitis			
subjects affected / exposed	22 / 2368 (0.93%)	23 / 2368 (0.97%)	
occurrences (all)	23	24	
Body tinea			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Bronchitis bacterial			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Candida infection			
subjects affected / exposed	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Bronchitis viral			

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Cellulitis		
subjects affected / exposed	9 / 2368 (0.38%)	14 / 2368 (0.59%)
occurrences (all)	11	14
Clostridium difficile infection		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Chronic sinusitis		
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)
occurrences (all)	2	1
Conjunctivitis		
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)
occurrences (all)	1	1
Cystitis		
subjects affected / exposed	6 / 2368 (0.25%)	12 / 2368 (0.51%)
occurrences (all)	7	13
Dacryocystitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Dengue fever		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Dermatitis infected		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Diverticulitis		
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)
occurrences (all)	1	0
Empyema		
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)
occurrences (all)	0	1
Erysipelas		
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)
occurrences (all)	3	6
Epiglottitis		

subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Eye infection bacterial			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Fungal balanitis			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Fungal infection			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Furuncle			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Gastroenteritis			
subjects affected / exposed	5 / 2368 (0.21%)	12 / 2368 (0.51%)	
occurrences (all)	5	12	
Gastroenteritis adenovirus			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Gastroenteritis viral			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Genital infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Genital infection fungal			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Gingivitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Groin infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Helicobacter infection			

subjects affected / exposed	1		
	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Hepatitis B			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
coon chiese (any		1	
Hepatitis C			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Herpes simplex			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
(4)	1	0	
Herpes zoster			
subjects affected / exposed	2 / 2368 (0.08%)	6 / 2368 (0.25%)	
occurrences (all)	2	7	
Hordeolum			
subjects affected / exposed	1 / 2368 (0.04%)	3 / 2368 (0.13%)	
occurrences (all)	1	3	
(4)	1	3	
Infected bite			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Infected dermal cyst			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
,	1		
Infected skin ulcer			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
(4)	1		
Infective exacerbation of chronic			
obstructive airways disease subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)			
occurrences (an)	0	1	
Influenza			
subjects affected / exposed	22 / 2368 (0.93%)	18 / 2368 (0.76%)	
occurrences (all)	23	20	

Klebsiella infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Labyrinthitis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Localised infection			
subjects affected / exposed	1 / 2368 (0.04%)	4 / 2368 (0.17%)	
occurrences (all)	2	4	
Lauren war der beschiede in Gestland			
Lower respiratory tract infection subjects affected / exposed	1 / 2260 (0.040/)	2 / 2260 /0 000/)	
	1 / 2368 (0.04%)	2 / 2368 (0.08%)	
occurrences (all)	1	2	
Lung abscess			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Lung infection			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Lyme disease			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Nail bed infection subjects affected / exposed	0 / 2260 / 0 000/)	4 / 2250 (0.040()	
	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Omphalitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Onychomycosis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Oral candidiasis			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
	_	_	

Orchitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Osteomyelitis			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Otitis externa			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Otitis media			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Otitis media chronic			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Paronychia subjects affected / exposed	0 / 2268 (0 00%)	1 / 2269 /0 040/)	
occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%) 2	
occarrences (an)		2	
Pathogen resistance			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Penile infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Periodontitis			
subjects affected / exposed	2 / 2368 (0.08%)	4 / 2368 (0.17%)	
occurrences (all)	2	4	
Peritonitis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Pharyngitis			
subjects affected / exposed	3 / 2368 (0.13%)	6 / 2368 (0.25%)	
occurrences (all)	3	6	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	

Pneumonia			
subjects affected / exposed	28 / 2368 (1.18%)	30 / 2368 (1.27%)	
occurrences (all)	28	32	
Post procedural infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Postoperative wound infection			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Pulpitis dental subjects affected / exposed	2 / 2269 (0 099)	0 / 2269 (0 000/)	
occurrences (all)	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (an)	2	0	
Pyelonephritis			
subjects affected / exposed	1 / 2368 (0.04%)	1 / 2368 (0.04%)	
occurrences (all)	1	1	
Pyelonephritis chronic			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Respiratory tract infection			
subjects affected / exposed	7 / 2368 (0.30%)	3 / 2368 (0.13%)	
occurrences (all)	7	3	
Doniratory tract infaction visal			
Respiratory tract infection viral subjects affected / exposed	7 / 2368 (0.30%)	6 / 2368 (0.25%)	
occurrences (all)		-	
occurrences (un)	10	10	
Rhinitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Septic embolus			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Septic shock			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Sialoadenitis			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
		-	

Sinusitis			
subjects affected / exposed	0 / 2368 (0.00%)	2 / 2368 (0.08%)	
occurrences (all)	0	2	
Skin infection			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Staphylococcal infection			
subjects affected / exposed	2 / 2368 (0.08%)	0 / 2368 (0.00%)	
occurrences (all)	2	0	
Tinea pedis subjects affected / exposed	2 / 2260 /0 000/)	1 / 2260 /0 040/)	
	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Tonsillitis			
subjects affected / exposed	2 / 2368 (0.08%)	1 / 2368 (0.04%)	
occurrences (all)	2	1	
Tooth infection			
subjects affected / exposed	2 / 2368 (0.08%)	2 / 2368 (0.08%)	
occurrences (all)	2	2	
Tracheitis			
subjects affected / exposed	0 / 2368 (0.00%)	1 / 2368 (0.04%)	
occurrences (all)	0	1	
Tracheobronchitis subjects affected / exposed	4 / 2260 /0 470/)	2 / 2262 / 2 224)	
	4 / 2368 (0.17%)	2 / 2368 (0.08%)	
occurrences (all)	4	2	
Upper respiratory tract infection			
subjects affected / exposed	15 / 2368 (0.63%)	15 / 2368 (0.63%)	
occurrences (all)	15	16	
Urinary tract infection			
subjects affected / exposed	34 / 2368 (1.44%)	31 / 2368 (1.31%)	
occurrences (all)	40	40	
Urinary tract infection enterococcal			
subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0	
Uroconsis			
Urosepsis subjects affected / exposed	1 / 2368 (0.04%)	0 / 2368 (0.00%)	
occurrences (all)	1	0 / 2308 (0.00%)	
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Viral infection subjects affected / exposed occurrences (all)	1 / 2368 (0.04%)	2 / 2368 (0.08%) 2	
Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 2368 (0.00%) 0	1 / 2368 (0.04%) 1	
Viral sinusitis subjects affected / exposed occurrences (all)	0 / 2368 (0.00%)	1 / 2368 (0.04%) 1	
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	2 / 2368 (0.08%) 6	0 / 2368 (0.00%) 0	
Wound infection subjects affected / exposed occurrences (all)	1 / 2368 (0.04%) 1	0 / 2368 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
	Amendment #2 included expanding the adverse event of interest category of amputations to also include: AEs leading to a risk for lower limb amputations ("preceding events"). This AE of interest was added based on discussion with regulatory authorities.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported