



Clinical trial results: NordiNet® International Outcome Study-Observational Prospective Study on Patients Treated With Norditropin®

Summary

EudraCT number	2008-001674-32
Trial protocol	FI
Global end of trial date	31 December 2016

Results information

Result version number	v1 (current)
This version publication date	16 February 2018
First version publication date	16 February 2018

Trial information

Trial identification

Sponsor protocol code	GHLIQUID-3676
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00960128
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novo Nordisk A/S
Sponsor organisation address	Novo Allé, Bagsvaerd, Denmark, 2880
Public contact	Clinical Reporting Anchor and Disclosure, Novo Nordisk A/S, clinicaltrials@novonordisk.com
Scientific contact	Clinical Reporting Anchor and Disclosure, Novo Nordisk A/S, clinicaltrials@novonordisk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 January 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2016
Global end of trial reached?	Yes
Global end of trial date	31 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To collect the post-marketing data on effectiveness and safety of real-life treatment with Norditropin.

Protection of trial subjects:

The study was carried out in accordance with the Declaration of Helsinki. The study reference documents were submitted for notification/approval to IEC/IRB and, if locally required, for notification/approval to regulatory authorities and data privacy agencies.

Background therapy:

Not applicable

Evidence for comparator:

Not applicable

Actual start date of recruitment	01 April 2006
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 33
Country: Number of subjects enrolled	Czech Republic: 1341
Country: Number of subjects enrolled	Denmark: 1186
Country: Number of subjects enrolled	Finland: 211
Country: Number of subjects enrolled	France: 3803
Country: Number of subjects enrolled	Germany: 7927
Country: Number of subjects enrolled	Hungary: 111
Country: Number of subjects enrolled	Ireland: 41
Country: Number of subjects enrolled	Israel: 152
Country: Number of subjects enrolled	Italy: 158
Country: Number of subjects enrolled	Lithuania: 108
Country: Number of subjects enrolled	Luxembourg: 2
Country: Number of subjects enrolled	Montenegro: 85
Country: Number of subjects enrolled	Netherlands: 153
Country: Number of subjects enrolled	Norway: 312
Country: Number of subjects enrolled	Russian Federation: 159
Country: Number of subjects enrolled	Serbia: 1373
Country: Number of subjects enrolled	Slovenia: 282
Country: Number of subjects enrolled	Spain: 6

Country: Number of subjects enrolled	Sweden: 1381
Country: Number of subjects enrolled	Switzerland: 534
Country: Number of subjects enrolled	United Kingdom: 866
Worldwide total number of subjects	20224
EEA total number of subjects	17921

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	40
Infants and toddlers (28 days-23 months)	557
Children (2-11 years)	12691
Adolescents (12-17 years)	4443
Adults (18-64 years)	2204
From 65 to 84 years	288
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The study included 469 clinics from 23 countries: Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Lithuania, Luxembourg, Montenegro, Netherlands, Norway, Russian Federation, Saudi Arabia, Serbia, Slovenia, Spain, Sweden, Switzerland, United Kingdom

Pre-assignment

Screening details:

This was an international, multi-centre, observational study based on all clinical data registered in NordiNet® as part of normal clinical practice. Patients were included in the study if they were treated with Norditropin® according to routine clinical practice.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Norditropin®
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Arm description:

The study population comprised children and adults treated with Norditropin® in the course of normal clinical practice. The overall study period was from 01 Apr 2006 to 31 Dec 2016.

Arm type	Experimental
Investigational medicinal product name	Somatropin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Somatropin as per routine clinical practice.

Number of subjects in period 1	Norditropin®
Started	20224
Completed	12938
Not completed	7286
Included in FAS but Excluded from EAS	7286

Baseline characteristics

Reporting groups

Reporting group title	Norditropin®
Reporting group description:	
The study population comprised children and adults treated with Norditropin® in the course of normal clinical practice. The overall study period was from 01 Apr 2006 to 31 Dec 2016.	

Reporting group values	Norditropin®	Total	
Number of subjects	20224	20224	
Age Categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	40	40	
Infants and toddlers (28 days-23 months)	557	557	
Children (2-11 years)	12691	12691	
Adolescents (12-17 years)	4443	4443	
Adults (18-64 years)	2204	2204	
From 65-84 years	288	288	
85 years and over	1	1	
Gender Categorical			
Units: Subjects			
Female	8678	8678	
Male	11546	11546	

Subject analysis sets

Subject analysis set title	Growth Hormone Deficiency (GHD) - Paediatric Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Paediatric patients with Growth Hormone Deficiency who were being treated with Norditropin®. The population represents effectiveness analysis set.	
Subject analysis set title	Small for Gestational Age (SGA) - Paediatric Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Paediatric patients with Small for Gestational Age (SGA) who were being treated with Norditropin®. The population represents effectiveness analysis set.	
Subject analysis set title	Turner Syndrome (TS) - Paediatric Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Paediatric patients with Turner Syndrome (TS) who were being treated with Norditropin®. The population represents effectiveness analysis set.	
Subject analysis set title	Chronic Renal Disease (CRD) - Paediatric Population
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Paediatric patients with chronic renal disease (CRD) who were being treated with Norditropin®. The population represents effectiveness analysis set.	
Subject analysis set title	Idiopathic Short Stature (ISS) - Paediatric Population

Subject analysis set type	Sub-group analysis
Subject analysis set description: Paediatric patients with idiopathic short stature (ISS) who were being treated with Norditropin®. The population represents effectiveness analysis set.	
Subject analysis set title	Noonan Syndrome (NS) - Paediatric Population
Subject analysis set type	Sub-group analysis
Subject analysis set description: Paediatric patients with Noonan Syndrome (NS) who were being treated with Norditropin®. The population represents effectiveness analysis set.	
Subject analysis set title	Prader-Willi Syndrome (PWS) - Paediatric Population
Subject analysis set type	Sub-group analysis
Subject analysis set description: Paediatric patients with Prader-Willi Syndrome (PWS) who were being treated with Norditropin®. The population represents effectiveness analysis set.	
Subject analysis set title	Adult Growth Hormone Deficiency (AGHD) - Adult Population
Subject analysis set type	Sub-group analysis
Subject analysis set description: Adult patients with adult growth hormone deficiency (AGHD) who were being treated with Norditropin®. The population represents effectiveness analysis set.	

Reporting group values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population
Number of subjects	7141	3200	936
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender Categorical Units: Subjects			
Female	2460	1463	936
Male	4681	1737	0

Reporting group values	Chronic Renal Disease (CRD) - Paediatric Population	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population
Number of subjects	200	317	106
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years)			

Adults (18-64 years) From 65-84 years 85 years and over			
Gender Categorical Units: Subjects			
Female	75	136	30
Male	125	181	76

Reporting group values	Prader-Willi Syndrome (PWS) - Paediatric Population	Adult Growth Hormone Deficiency (AGHD) - Adult Population	
Number of subjects	67	971	
Age Categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Gender Categorical Units: Subjects			
Female	28	434	
Male	39	537	

End points

End points reporting groups

Reporting group title	Norditropin®
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Reporting group description:

The study population comprised children and adults treated with Norditropin® in the course of normal clinical practice. The overall study period was from 01 Apr 2006 to 31 Dec 2016.

Subject analysis set title	Growth Hormone Deficiency (GHD) - Paediatric Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Paediatric patients with Growth Hormone Deficiency who were being treated with Norditropin®. The population represents effectiveness analysis set.

Subject analysis set title	Small for Gestational Age (SGA) - Paediatric Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Paediatric patients with Small for Gestational Age (SGA) who were being treated with Norditropin®. The population represents effectiveness analysis set.

Subject analysis set title	Turner Syndrome (TS) - Paediatric Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Paediatric patients with Turner Syndrome (TS) who were being treated with Norditropin®. The population represents effectiveness analysis set.

Subject analysis set title	Chronic Renal Disease (CRD) - Paediatric Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Paediatric patients with chronic renal disease (CRD) who were being treated with Norditropin®. The population represents effectiveness analysis set.

Subject analysis set title	Idiopathic Short Stature (ISS) - Paediatric Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Paediatric patients with idiopathic short stature (ISS) who were being treated with Norditropin®. The population represents effectiveness analysis set.

Subject analysis set title	Noonan Syndrome (NS) - Paediatric Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Paediatric patients with Noonan Syndrome (NS) who were being treated with Norditropin®. The population represents effectiveness analysis set.

Subject analysis set title	Prader-Willi Syndrome (PWS) - Paediatric Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Paediatric patients with Prader-Willi Syndrome (PWS) who were being treated with Norditropin®. The population represents effectiveness analysis set.

Subject analysis set title	Adult Growth Hormone Deficiency (AGHD) - Adult Population
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Subject analysis set type	Sub-group analysis
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Subject analysis set description:

Adult patients with adult growth hormone deficiency (AGHD) who were being treated with Norditropin®. The population represents effectiveness analysis set.

Primary: Change from baseline in Height Standard Deviation Scores (SDS) - Paediatric population

End point title	Change from baseline in Height Standard Deviation Scores (SDS) - Paediatric population ^[1]
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End point description:

Height standard deviation scores were calculated as per national standard. Analysis was based on the

effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.

End point type	Primary
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End point timeframe:

Up to 10 Years of follow up

Notes:

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

Justification: This was an observational, non-interventional study. Only descriptive statistics was performed.

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: Standard Deviation Scores				
arithmetic mean (standard deviation)				
Baseline (n=7141,3200,936,200,317,106,67)	-2.55 (± 1.10)	-2.97 (± 0.91)	-2.66 (± 0.93)	-2.74 (± 1.17)
Year 1 Follow Up (n=5173,2231,725,136,245,70,43)	0.69 (± 0.56)	0.65 (± 0.44)	0.54 (± 0.36)	0.61 (± 1.19)
Year 2 Follow Up (n=4403,1882,642,94,190,56,30)	1.09 (± 0.75)	1.01 (± 0.57)	0.81 (± 0.52)	0.9 (± 0.76)
Year 3 Follow Up (n=3574,1538,540,69,139,40,28)	1.36 (± 0.85)	1.29 (± 0.65)	0.99 (± 0.61)	1.14 (± 0.97)
Year 4 Follow Up (n=2683,1195,429,44,94,37,25)	1.56 (± 0.95)	1.46 (± 0.69)	1.04 (± 0.66)	1.21 (± 1.14)
Year 5 Follow Up (n=1916,897,344,31,65,25,17)	1.72 (± 1.05)	1.64 (± 0.71)	1.12 (± 0.67)	1.6 (± 1.07)
Year 6 Follow Up (n=1388,644,249,22,40,16,12)	1.87 (± 1.11)	1.8 (± 0.77)	1.16 (± 0.65)	1.92 (± 1.13)
Year 7 Follow Up (n=941,447,184,14,28,10,11)	2.03 (± 1.15)	1.94 (± 0.79)	1.07 (± 0.69)	1.95 (± 1.17)
Year 8 Follow Up (n=648,280,135,14,18,7,10)	2.21 (± 1.21)	2.04 (± 0.77)	0.98 (± 0.68)	2.14 (± 1.07)
Year 9 Follow Up (n=456,186,85,9,9,7,7)	2.26 (± 1.25)	2.01 (± 0.76)	0.88 (± 0.6)	2.54 (± 1.08)
Year 10 Follow Up (n=273,96,47,7,9,4,6)	2.41 (± 1.35)	1.93 (± 0.89)	0.77 (± 0.78)	2.8 (± 0.74)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	317	106	67
Units: Standard Deviation Scores			
arithmetic mean (standard deviation)			
Baseline (n=7141,3200,936,200,317,106,67)	-2.82 (± 0.99)	-2.83 (± 1.13)	-1.94 (± 1.48)
Year 1 Follow Up (n=5173,2231,725,136,245,70,43)	0.52 (± 0.38)	0.51 (± 0.38)	0.85 (± 0.9)

Year 2 Follow Up (n=4403,1882,642,94,190,56,30)	0.89 (± 0.59)	0.83 (± 0.64)	1.19 (± 1.13)	
Year 3 Follow Up (n=3574,1538,540,69,139,40,28)	1.09 (± 0.7)	1.01 (± 0.69)	1.23 (± 1.05)	
Year 4 Follow Up (n=2683,1195,429,44,94,37,25)	1.28 (± 0.74)	1.07 (± 0.7)	1.34 (± 1.22)	
Year 5 Follow Up (n=1916,897,344,31,65,25,17)	1.43 (± 0.81)	1.18 (± 0.82)	1.43 (± 1.26)	
Year 6 Follow Up (n=1388,644,249,22,40,16,12)	1.71 (± 0.85)	0.99 (± 0.75)	1.9 (± 1.01)	
Year 7 Follow Up (n=941,447,184,14,28,10,11)	1.86 (± 0.99)	0.93 (± 1.03)	1.26 (± 1.07)	
Year 8 Follow Up (n=648,280,135,14,18,7,10)	1.7 (± 0.68)	1.29 (± 1.02)	1.16 (± 1.06)	
Year 9 Follow Up (n=456,186,85,9,9,7,7)	1.74 (± 0.82)	1.05 (± 0.8)	1.63 (± 1.36)	
Year 10 Follow Up (n=273,96,47,7,9,4,6)	1.28 (± 0.96)	1.21 (± 0.51)	1.8 (± 1.25)	

Statistical analyses

No statistical analyses for this end point

Primary: Change from baseline in waist circumference - Adult population

End point title	Change from baseline in waist circumference - Adult
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.

End point type	Primary
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End point timeframe:

Up to 10 years of follow up

Notes:

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

Justification: This was an observational, non-interventional study. Only descriptive statistics was performed.

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: cm				
arithmetic mean (standard deviation)				
Female: Baseline (n=241)	95.76 (± 15.77)			
Female: Year 1 follow-up (n=130)	-1.32 (± 5.29)			
Female: Year 2 follow-up (n=93)	-0.33 (± 6.88)			
Female: Year 3 follow-up (n=64)	0.68 (± 7.36)			
Female: Year 4 follow-up (n=55)	-0.2 (± 8.32)			
Female: Year 5 follow-up (n=47)	-0.51 (± 7.92)			
Female: Year 6 follow-up (n=38)	-0.33 (± 9)			

Female: Year 7 follow-up (n=34)	-1.94 (± 9.03)			
Female: Year 8 follow-up (n=24)	1.04 (± 10.93)			
Female: Year 9 follow-up (n=20)	1.1 (± 12.39)			
Female: Year 10 follow-up (n=16)	1.47 (± 10.66)			
Male: Baseline (n=290)	102.29 (± 13.21)			
Male: Year 1 follow-up (n=124)	-0.76 (± 6.56)			
Male: Year 2 follow-up (n=104)	-1.41 (± 5.94)			
Male: Year 3 follow-up (n=71)	-0.12 (± 6.43)			
Male: Year 4 follow-up (n=63)	0.1 (± 7.15)			
Male: Year 5 follow-up (n=50)	-0.24 (± 7.32)			
Male: Year 6 follow-up (n=35)	1.2 (± 5.95)			
Male: Year 7 follow-up (n=31)	-0.18 (± 6.88)			
Male: Year 8 follow-up (n=31)	2 (± 8.24)			
Male: Year 9 follow-up (n=19)	-2.74 (± 11.89)			
Male: Year 10 follow-up (n=19)	-0.37 (± 7.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in body weight - Adult population

End point title	Change from baseline in body weight - Adult population			
End point description:	Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.			
End point type	Secondary			
End point timeframe:	Up to 10 years of follow up			

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: kg				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=269)	-0.19 (± 8.3)			
Female: Year 2 follow-up (n=206)	1.46 (± 13.3)			
Female: Year 3 follow-up (n=166)	1.51 (± 11.26)			
Female: Year 4 follow-up (n=134)	1.05 (± 7.85)			
Female: Year 5 follow-up (n=112)	0.32 (± 7.51)			
Female: Year 6 follow-up (n=97)	0.67 (± 13.47)			
Female: Year 7 follow-up (n=82)	0.5 (± 8.2)			
Female: Year 8 follow-up (n=63)	0.27 (± 14.47)			

Female: Year 9 follow-up (n=56)	0.94 (± 8.37)			
Female: Year 10 follow-up (n=42)	-3.38 (± 22.32)			
Male: Year 1 follow-up (n=311)	0.45 (± 10.69)			
Male: Year 2 follow-up (n=262)	0.23 (± 6.66)			
Male: Year 3 follow-up (n=193)	1.27 (± 14.18)			
Male: Year 4 follow-up (n=177)	1.06 (± 10.04)			
Male: Year 5 follow-up (n=139)	0.79 (± 10.53)			
Male: Year 6 follow-up (n=120)	1.56 (± 9.10)			
Male: Year 7 follow-up (n=94)	0.88 (± 10.41)			
Male: Year 8 follow-up (n=90)	0.03 (± 16.37)			
Male: Year 9 follow-up (n=66)	-2.39 (± 23.42)			
Male: Year 10 follow-up (n=52)	-1.14 (± 22.36)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in weight SDS - Paediatric population

End point title	Change from baseline in weight SDS - Paediatric population
End point description:	Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.
End point type	Secondary
End point timeframe:	Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: standard deviation scores				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=2452,1114,386,46,117,42,25)	0.44 (± 0.62)	0.54 (± 0.53)	0.32 (± 0.49)	0.45 (± 0.64)
Year 2 follow-up (n=2008,912,335,29,86,32,18)	0.82 (± 0.86)	0.87 (± 0.69)	0.64 (± 0.64)	0.72 (± 0.7)
Year 3 follow-up (n=1508,694,270,22,63,24,17)	1.08 (± 1.02)	1.12 (± 0.8)	0.85 (± 0.76)	1.14 (± 0.83)
Year 4 follow-up (n=1066,510,207,12,37,17,13)	1.24 (± 1.12)	1.28 (± 0.91)	1.01 (± 0.83)	1 (± 0.9)
Year 5 follow-up (n=733,364,162,6,25,10,7)	1.46 (± 1.26)	1.42 (± 0.92)	1.1 (± 0.82)	1.04 (± 1.11)

Year 6 follow-up (n=492,256,125,6,15,6,5)	1.58 (± 1.37)	1.59 (± 0.88)	1.33 (± 0.89)	1.34 (± 1.41)
Year 7 follow-up (n=323,174,88,3,7,3,6)	1.67 (± 1.49)	1.78 (± 1.06)	1.39 (± 0.91)	1.13 (± 1.45)
Year 8 follow-up (n=234,100,71,3,7,1,7)	1.79 (± 1.66)	1.99 (± 1.03)	1.47 (± 0.92)	1.59 (± 1.33)
Year 9 follow-up (n=160,66,42,2,1,2,4)	1.86 (± 1.39)	2.07 (± 0.93)	1.54 (± 0.86)	1.43 (± 2.16)
Year 10 follow-up (n=95,34,28,1,3,2,3)	2.07 (± 1.29)	2.05 (± 1.06)	1.44 (± 0.82)	2.75 (± 99999.9999)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: standard deviation scores				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=2452,1114,386,46,117,42,25)	0.31 (± 0.57)	0.25 (± 0.38)	0.79 (± 0.96)	
Year 2 follow-up (n=2008,912,335,29,86,32,18)	0.69 (± 0.72)	0.6 (± 0.65)	1.3 (± 1.51)	
Year 3 follow-up (n=1508,694,270,22,63,24,17)	0.86 (± 0.87)	0.75 (± 0.78)	1.52 (± 1.76)	
Year 4 follow-up (n=1066,510,207,12,37,17,13)	0.93 (± 0.88)	0.74 (± 0.73)	2.21 (± 1.79)	
Year 5 follow-up (n=733,364,162,6,25,10,7)	1.07 (± 0.92)	0.97 (± 0.83)	1.68 (± 1.56)	
Year 6 follow-up (n=492,256,125,6,15,6,5)	1.65 (± 1.21)	0.6 (± 0.76)	2.71 (± 1.71)	
Year 7 follow-up (n=323,174,88,3,7,3,6)	1.68 (± 0.91)	0.85 (± 1.19)	1.67 (± 1.7)	
Year 8 follow-up (n=234,100,71,3,7,1,7)	1.66 (± 1.84)	1.6 (± 99999.9999)	1.28 (± 1.73)	
Year 9 follow-up (n=160,66,42,2,1,2,4)	1.68 (± 99999.9999)	1.4 (± 0.34)	1.75 (± 2.38)	
Year 10 follow-up (n=95,34,28,1,3,2,3)	1.11 (± 2.03)	1.32 (± 0.34)	2.27 (± 2.89)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in HbA1c - Paediatric population

End point title	Change from baseline in HbA1c - Paediatric population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: percentage of HbA1c				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=734,411,149,18,39,10,5)	0.04 (± 0.47)	0.05 (± 0.46)	0.1 (± 0.51)	0.36 (± 1.28)
Year 2 follow-up (n=583,309,119,15,29,8,4)	0.06 (± 0.49)	0.02 (± 0.53)	0.09 (± 0.54)	0.22 (± 0.45)
Year 3 follow-up (n=444,235,110,9,22,4,2)	0.04 (± 0.49)	0.05 (± 0.57)	0.05 (± 0.66)	-0.17 (± 0.77)
Year 4 follow-up (n=308,169,77,5,10,1,0)	-0 (± 0.52)	0.05 (± 0.65)	-0.01 (± 0.56)	0.19 (± 0.75)
Year 5 follow-up (n=196,126,66,3,6,1,1)	-0.05 (± 0.57)	0.14 (± 0.45)	0.04 (± 0.6)	0.3 (± 0)
Year 6 follow-up (n=134,91,41,3,2,0,0)	0.02 (± 0.51)	0.08 (± 0.43)	0.08 (± 0.68)	0.5 (± 0.56)
Year 7 follow-up (n=77,71,29,1,1,1,0)	0.01 (± 0.7)	0.07 (± 0.49)	0.06 (± 0.65)	0 (± 99999.999)
Year 8 follow-up (n=54,47,18,2,3,1,0)	0.08 (± 0.43)	0.12 (± 0.42)	0.22 (± 0.54)	0.1 (± 0.28)
Year 9 follow-up (n=34,33,9,1,0,1,0)	0.11 (± 0.41)	-0.04 (± 0.34)	1.3 (± 2.87)	-0.3 (± 99999.999)
Year 10 follow-up (n=13,15,4,1,0,1,0)	0.21 (± 0.33)	-0.04 (± 0.33)	-0.05 (± 0.62)	0.1 (± 99999.999)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: percentage of HbA1c				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=734,411,149,18,39,10,5)	0.02 (± 0.37)	0.15 (± 0.4)	0.1 (± 1.07)	
Year 2 follow-up (n=583,309,119,15,29,8,4)	0.09 (± 0.42)	0.24 (± 0.45)	-0.47 (± 0.84)	
Year 3 follow-up (n=444,235,110,9,22,4,2)	0.06 (± 0.51)	-0.1 (± 0)	0.6 (± 0.57)	
Year 4 follow-up (n=308,169,77,5,10,1,0)	-0.02 (± 0.41)	-0.1 (± 99999.999)	99999.999 (± 99999.999)	
Year 5 follow-up (n=196,126,66,3,6,1,1)	0.05 (± 0.15)	0 (± 99999.999)	0.4 (± 99999.999)	
Year 6 follow-up (n=134,91,41,3,2,0,0)	0.35 (± 0.49)	99999.999 (± 99999.999)	99999.999 (± 99999.999)	
Year 7 follow-up (n=77,71,29,1,1,1,0)	0 (± 99999.999)	0.6 (± 99999.999)	99999.999 (± 99999.999)	

Year 8 follow-up (n=54,47,18,2,3,1,0)	-0.6 (± 0.85)	0.5 (± 99999.999)	99999.999 (± 99999.999)
Year 9 follow-up (n=34,33,9,1,0,1,0)	99999.999 (± 99999.999)	0.3 (± 99999.999)	99999.999 (± 99999.999)
Year 10 follow-up (n=13,15,4,1,0,1,0)	99999.999 (± 99999.999)	0.3 (± 99999.999)	99999.999 (± 99999.999)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in fasting blood glucose - Paediatric population

End point title	Change from baseline in fasting blood glucose - Paediatric population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=466,261,75,13,17,2,3)	0.33 (± 0.95)	0.21 (± 1.04)	0.26 (± 0.76)	0.44 (± 0.89)
Year 2 follow-up (n=325,168,74,7,12,2,0)	0.3 (± 1.01)	0.34 (± 1.03)	0.41 (± 0.79)	0.44 (± 0.51)
Year 3 follow-up (n=209,117,45,7,5,2,4)	0.35 (± 1.26)	0.47 (± 1.3)	0.75 (± 1.69)	0.31 (± 0.52)
Year 4 follow-up (n=152,79,40,4,1,0,0)	0.3 (± 1.23)	0.52 (± 1.37)	0.51 (± 0.63)	0.43 (± 1.49)
Year 5 follow-up (n=99,59,28,2,1,0,0)	0.49 (± 1.12)	-0.18 (± 5.38)	0.46 (± 1.13)	0.95 (± 0.93)
Year 6 follow-up (n=90,41,24,3,0,0,0)	0.32 (± 1.05)	0.06 (± 0.91)	0.38 (± 0.96)	0.96 (± 0.81)
Year 7 follow-up (n=75,22,23,1,0,0,0)	0.52 (± 1.03)	0.41 (± 0.76)	0.47 (± 0.96)	1.33 (± 9999.999)
Year 8 follow-up (n=60,12,11,2,0,0,0)	0.7 (± 1.18)	0.31 (± 0.54)	0.48 (± 1.6)	0.8 (± 0.04)
Year 9 follow-up (n=39,7,6,1,0,0,0)	0.55 (± 1.15)	0.05 (± 0.83)	0.44 (± 0.89)	1.17 (± 9999.999)
Year 10 follow-up (n=21,1,1,1,0,0,0)	0.5 (± 1.3)	0.44 (± 9999.999)	0.39 (± 9999.999)	1 (± 9999.999)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=466,261,75,13,17,2,3)	0.22 (± 0.9)	-0.87 (± 1.23)	-0.17 (± 0.47)	
Year 2 follow-up (n=325,168,74,7,12,2,0)	0.6 (± 0.71)	0.62 (± 0.16)	9999.999 (± 9999.999)	
Year 3 follow-up (n=209,117,45,7,5,2,4)	0.21 (± 1.75)	0.71 (± 0.28)	-0.27 (± 0.3)	
Year 4 follow-up (n=152,79,40,4,1,0,0)	0 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 5 follow-up (n=99,59,28,2,1,0,0)	0.1 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 6 follow-up (n=90,41,24,3,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 7 follow-up (n=75,22,23,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 8 follow-up (n=60,12,11,2,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 9 follow-up (n=39,7,6,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 10 follow-up (n=21,1,1,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in total cholesterol - Paediatric population

End point title	Change from baseline in total cholesterol - Paediatric population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200

Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=443,193,69,19,18,7,0)	-0.14 (± 0.73)	-0.06 (± 0.61)	-0.24 (± 0.58)	-0.45 (± 0.86)
Year 2 follow-up (n=314,124,48,12,14,3,0)	-0.27 (± 0.82)	-0.23 (± 0.65)	-0.15 (± 0.72)	-0.87 (± 0.75)
Year 3 follow-up (n=202,67,31,7,6,3,3)	-0.39 (± 0.9)	-0.12 (± 0.63)	-0.13 (± 0.9)	-0.84 (± 0.84)
Year 4 follow-up (n=143,60,24,6,2,2,0)	-0.39 (± 0.94)	-0.24 (± 0.64)	0.01 (± 0.88)	-0.28 (± 0.51)
Year 5 follow-up (n=87,49,12,3,1,1,0)	-0.35 (± 0.75)	-0.23 (± 0.75)	-0.1 (± 0.71)	-0.63 (± 0.24)
Year 6 follow-up (n=79,38,10,2,0,1,0)	-0.16 (± 0.75)	-0.27 (± 0.79)	0.25 (± 0.69)	-1 (± 0.68)
Year 7 follow-up (n=63,20,7,2,0,0,0)	-0.3 (± 1.13)	-0.34 (± 0.63)	0.7 (± 0.93)	-3.74 (± 3.79)
Year 8 follow-up (n=48,18,5,2,0,0,0)	-0.19 (± 0.67)	-0.33 (± 0.71)	-0.23 (± 1.25)	-4.13 (± 3.35)
Year 9 follow-up (n=26,20,2,1,0,0,0)	-0.39 (± 0.88)	-0.27 (± 0.68)	0.11 (± 1.29)	-1.14 (± 9999.999)
Year 10 follow-up (n=12,8,1,1,0,1,0)	-0.19 (± 0.8)	-0.15 (± 0.46)	0.88 (± 9999.999)	-2.14 (± 9999.999)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=443,193,69,19,18,7,0)	-0.04 (± 0.62)	-0.46 (± 0.69)	9999.999 (± 9999.999)	
Year 2 follow-up (n=314,124,48,12,14,3,0)	-0.09 (± 1.08)	-0.89 (± 0.75)	9999.999 (± 9999.999)	
Year 3 follow-up (n=202,67,31,7,6,3,3)	0.47 (± 0.97)	-1.5 (± 1.42)	-0.16 (± 0.73)	
Year 4 follow-up (n=143,60,24,6,2,2,0)	0.3 (± 0.57)	-1.35 (± 0.49)	9999.999 (± 9999.999)	
Year 5 follow-up (n=87,49,12,3,1,1,0)	-0.2 (± 9999.999)	-1.13 (± 9999.999)	9999.999 (± 9999.999)	
Year 6 follow-up (n=79,38,10,2,0,1,0)	9999.999 (± 9999.999)	-0.77 (± 9999.999)	9999.999 (± 9999.999)	
Year 7 follow-up (n=63,20,7,2,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 8 follow-up (n=48,18,5,2,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 9 follow-up (n=26,20,2,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 10 follow-up (n=12,8,1,1,0,1,0)	9999.999 (± 9999.999)	-1.38 (± 9999.999)	9999.999 (± 9999.999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in HDL cholesterol - Paediatric population

End point title	Change from baseline in HDL cholesterol - Paediatric population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.

End point type	Secondary
End point timeframe:	
Up to 10 years of follow up	

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=233,110,30,6,5,3,0)	-0.06 (± 0.44)	0.04 (± 0.34)	0 (± 0.35)	-0.04 (± 0.12)
Year 2 follow-up (n=168,64,19,4,6,2,0)	-0.06 (± 0.34)	-0.04 (± 0.51)	0.07 (± 0.41)	-0.04 (± 0.42)
Year 3 follow-up (n=106,34,13,3,3,0,3)	-0.12 (± 0.36)	0.02 (± 0.35)	0.02 (± 0.21)	0.08 (± 0.55)
Year 4 follow-up (n=65,37,9,3,2,0,0)	-0.13 (± 0.41)	-0.06 (± 0.66)	0.21 (± 0.37)	0 (± 0.49)
Year 5 follow-up (n=31,25,4,1,1,0,0)	-0.04 (± 0.31)	0.04 (± 0.37)	0.2 (± 0.57)	-0.34 (± 9999.999)
Year 6 follow-up (n=29,20,2,1,0,0,0)	0.01 (± 0.34)	0.05 (± 0.46)	0.43 (± 0.05)	-0.28 (± 9999.999)
Year 7 follow-up (n=24,13,3,1,0,0,0)	-0.09 (± 0.98)	-0.04 (± 0.32)	0.04 (± 0.12)	-0.08 (± 9999.999)
Year 8 follow-up (n=18,13,1,1,0,0,0)	-0.31 (± 0.8)	0.29 (± 0.89)	0.13 (± 9999.999)	-0.05 (± 9999.999)
Year 9 follow-up (n=8,13,1,0,0,0,0)	-0.43 (± 1.16)	-0.05 (± 0.21)	0.18 (± 9999.999)	9999.999 (± 9999.999)
Year 10 follow-up (n=2,6,0,0,0,0,0)	0.26 (± 0.99)	0.67 (± 0.68)	9999.999 (± 9999.999)	9999.999 (± 9999.999)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=233,110,30,6,5,3,0)	-0.01 (± 0.16)	-0.03 (± 0.27)	9999.999 (± 9999.999)	
Year 2 follow-up (n=168,64,19,4,6,2,0)	-0.01 (± 0.38)	-0.09 (± 0.13)	9999.999 (± 9999.999)	
Year 3 follow-up (n=106,34,13,3,3,0,3)	0.05 (± 0.13)	9999.999 (± 9999.999)	0.06 (± 0.22)	
Year 4 follow-up (n=65,37,9,3,2,0,0)	0.03 (± 0.1)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	

Year 5 follow-up (n=31,25,4,1,1,0,0)	-0.42 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 6 follow-up (n=29,20,2,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 7 follow-up (n=24,13,3,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 8 follow-up (n=18,13,1,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 9 follow-up (n=8,13,1,0,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 10 follow-up (n=2,6,0,0,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in LDL cholesterol - Paediatric population

End point title	Change from baseline in LDL cholesterol - Paediatric population
End point description:	Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.
End point type	Secondary
End point timeframe:	Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=218,105,30,5,5,3,0)	-0.22 (± 0.73)	-0.08 (± 0.65)	-0.27 (± 0.52)	-0.4 (± 0.37)
Year 2 follow-up (n=151,60,18,3,6,2,0)	-0.26 (± 0.64)	-0.17 (± 0.58)	-0.06 (± 0.65)	-1.86 (± 1.55)
Year 3 follow-up (n=95,30,13,3,3,0,3)	-0.41 (± 0.79)	-0.28 (± 0.44)	-0.41 (± 0.88)	-0.28 (± 1.14)
Year 4 follow-up (n=59,34,9,3,2,0,0)	-0.46 (± 0.8)	-0.26 (± 0.71)	0.15 (± 0.79)	-0.48 (± 0.48)
Year 5 follow-up (n=30,25,4,1,1,0,0)	-0.4 (± 0.62)	-0.4 (± 0.6)	-0.69 (± 0.72)	-0.96 (± 9999.999)
Year 6 follow-up (n=30,19,3,1,0,0,0)	-0.35 (± 0.76)	-0.26 (± 0.49)	-0.53 (± 0.82)	-1.5 (± 9999.999)
Year 7 follow-up (n=24,12,4,1,0,0,0)	-0.36 (± 0.95)	-0.32 (± 0.57)	-0.32 (± 1.13)	-5.98 (± 9999.999)
Year 8 follow-up (n=17,11,2,1,0,0,0)	-0.51 (± 0.57)	-0.2 (± 0.59)	-0.94 (± 1.12)	-6.03 (± 9999.999)
Year 9 follow-up (n=8,13,1,0,0,0,0)	-0.18 (± 1.04)	-0.29 (± 0.65)	-1.71 (± 9999.999)	9999.999 (± 9999.999)

Year 10 follow-up (n=1,5,0,0,0,0,0)	0.1 (± 9999.999)	-0.93 (± 1.06)	9999.999 (± 9999.999)	9999.999 (± 9999.999)
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End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=218,105,30,5,5,3,0)	-0.58 (± 1.86)	-0.03 (± 0.23)	9999.999 (± 9999.999)	
Year 2 follow-up (n=151,60,18,3,6,2,0)	0.02 (± 2.14)	-0.9 (± 0.57)	9999.999 (± 9999.999)	
Year 3 follow-up (n=95,30,13,3,3,0,3)	1.18 (± 1.03)	9999.999 (± 9999.999)	-0.15 (± 0.44)	
Year 4 follow-up (n=59,34,9,3,2,0,0)	0.7 (± 1.13)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 5 follow-up (n=30,25,4,1,1,0,0)	0 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 6 follow-up (n=30,19,3,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 7 follow-up (n=24,12,4,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 8 follow-up (n=17,11,2,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 9 follow-up (n=8,13,1,0,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 10 follow-up (n=1,5,0,0,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in triglycerides - Paediatric population

End point title	Change from baseline in triglycerides - Paediatric population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=267,114,44,8,17,6,0)	0.18 (± 0.62)	0.09 (± 0.72)	0.12 (± 0.38)	0.64 (± 1.01)
Year 2 follow-up (n=176,65,27,4,11,2,0)	0.15 (± 0.65)	-0.07 (± 0.52)	0.06 (± 0.62)	-0.82 (± 1.36)
Year 3 follow-up (n=107,29,18,2,6,3,3)	0.12 (± 0.77)	0.21 (± 0.65)	0.33 (± 0.62)	-0.03 (± 0.81)
Year 4 follow-up (n=67,35,14,1,1,1,0)	0.29 (± 0.74)	0.11 (± 0.49)	0.17 (± 0.95)	1.31 (± 9999.999)
Year 5 follow-up (n=37,24,6,1,1,0,0)	0.29 (± 0.56)	0.18 (± 0.55)	0.13 (± 0.27)	1.22 (± 9999.999)
Year 6 follow-up (n=30,18,4,1,0,0,0)	0.31 (± 0.86)	0.01 (± 0.61)	0.1 (± 1.19)	0.5 (± 9999.999)
Year 7 follow-up (n=20,12,4,1,0,0,0)	0.35 (± 0.62)	0.13 (± 0.58)	0.72 (± 1.32)	-3.73 (± 9999.999)
Year 8 follow-up (n=15,9,2,1,0,0,0)	0.28 (± 0.56)	-0.04 (± 0.6)	0.93 (± 0.19)	-3.91 (± 9999.999)
Year 9 follow-up (n=8,4,1,0,0,0,0)	0.21 (± 0.38)	-0.41 (± 0.48)	1.57 (± 9999.999)	9999.999 (± 9999.999)
Year 10 follow-up (n=1,0,0,0,0,0,0)	0.38 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: mmol/l				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=267,114,44,8,17,6,0)	-0.01 (± 0.55)	0.2 (± 0.24)	9999.999 (± 9999.999)	
Year 2 follow-up (n=176,65,27,4,11,2,0)	0.02 (± 0.56)	0.05 (± 0.64)	9999.999 (± 9999.999)	
Year 3 follow-up (n=107,29,18,2,6,3,3)	-0.46 (± 0.52)	0.28 (± 0.28)	-0.15 (± 0.33)	
Year 4 follow-up (n=67,35,14,1,1,1,0)	-0.04 (± 9999.999)	0 (± 9999.999)	9999.999 (± 9999.999)	
Year 5 follow-up (n=37,24,6,1,1,0,0)	0.39 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 6 follow-up (n=30,18,4,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 7 follow-up (n=20,12,4,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 8 follow-up (n=15,9,2,1,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 9 follow-up (n=8,4,1,0,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	
Year 10 follow-up (n=1,0,0,0,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in HbA1c - Adult population

End point title	Change from baseline in HbA1c - Adult population
End point description:	
Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.	
End point type	Secondary
End point timeframe:	
Up to 10 years of follow up	

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: percentage of HbA1c				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=141)	-0.03 (± 0.48)			
Female: Year 2 follow-up (n=104)	0.03 (± 0.5)			
Female: Year 3 follow-up (n=73)	-0.05 (± 0.71)			
Female: Year 4 follow-up (n=64)	0.13 (± 0.86)			
Female: Year 5 follow-up (n=55)	0.18 (± 0.76)			
Female: Year 6 follow-up (n=46)	0.09 (± 0.7)			
Female: Year 7 follow-up (n=33)	0.12 (± 0.68)			
Female: Year 8 follow-up (n=26)	0.1 (± 0.76)			
Female: Year 9 follow-up (n=18)	0.03 (± 0.42)			
Female: Year 10 follow-up (n=19)	0.02 (± 1)			
Male: Year 1 follow-up (n=155)	0.01 (± 0.43)			
Male: Year 2 follow-up (n=140)	-0.04 (± 0.55)			
Male: Year 3 follow-up (n=100)	0.08 (± 0.37)			
Male: Year 4 follow-up (n=83)	0.1 (± 0.7)			
Male: Year 5 follow-up (n=63)	0.05 (± 0.53)			
Male: Year 6 follow-up (n=56)	0.12 (± 0.4)			
Male: Year 7 follow-up (n=48)	-0.03 (± 0.5)			
Male: Year 8 follow-up (n=40)	0.13 (± 0.74)			
Male: Year 9 follow-up (n=22)	0.23 (± 0.64)			
Male: Year 10 follow-up (n=13)	-0.01 (± 0.65)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in fasting blood glucose - Adult population

End point title	Change from baseline in fasting blood glucose - Adult population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: mmol/l				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=102)	0.16 (± 1.19)			
Female: Year 2 follow-up (n=71)	0.28 (± 1.76)			
Female: Year 3 follow-up (n=58)	0.4 (± 0.83)			
Female: Year 4 follow-up (n=49)	1.22 (± 4.99)			
Female: Year 5 follow-up (n=38)	0.24 (± 0.82)			
Female: Year 6 follow-up (n=28)	0.42 (± 1.02)			
Female: Year 7 follow-up (n=23)	0.15 (± 1.86)			
Female: Year 8 follow-up (n=16)	0.52 (± 0.96)			
Female: Year 9 follow-up (n=15)	0.27 (± 0.82)			
Female: Year 10 follow-up (n=11)	-0.34 (± 2.91)			
Male: Year 1 follow-up (n=121)	0.23 (± 1.15)			
Male: Year 2 follow-up (n=90)	0.21 (± 0.86)			
Male: Year 3 follow-up (n=71)	0.18 (± 0.76)			
Male: Year 4 follow-up (n=61)	0.21 (± 1.06)			
Male: Year 5 follow-up (n=43)	0.47 (± 0.86)			
Male: Year 6 follow-up (n=38)	0.6 (± 1.21)			
Male: Year 7 follow-up (n=31)	0.55 (± 0.85)			
Male: Year 8 follow-up (n=29)	0.84 (± 2.48)			
Male: Year 9 follow-up (n=17)	0.26 (± 1.4)			
Male: Year 10 follow-up (n=18)	1.22 (± 2.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in total cholesterol - Adult population

End point title	Change from baseline in total cholesterol - Adult population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: mmol/l				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=132)	0.03 (± 0.88)			
Female: Year 2 follow-up (n=103)	-0.06 (± 1.09)			
Female: Year 3 follow-up (n=79)	-0.07 (± 1.24)			
Female: Year 4 follow-up (n=64)	-0.16 (± 1.07)			
Female: Year 5 follow-up (n=58)	-0.19 (± 1.15)			
Female: Year 6 follow-up (n=48)	-0.2 (± 0.93)			
Female: Year 7 follow-up (n=36)	-0.53 (± 1.46)			
Female: Year 8 follow-up (n=27)	-0.46 (± 1.29)			
Female: Year 9 follow-up (n=30)	-0.43 (± 1.58)			
Female: Year 10 follow-up (n=18)	-0.52 (± 1.63)			
Male: Year 1 follow-up (n=160)	-0.25 (± 0.94)			
Male: Year 2 follow-up (n=144)	-0.44 (± 1.01)			
Male: Year 3 follow-up (n=106)	-0.37 (± 1.24)			
Male: Year 4 follow-up (n=87)	-0.39 (± 1.15)			
Male: Year 5 follow-up (n=72)	-0.24 (± 1.02)			
Male: Year 6 follow-up (n=62)	-0.51 (± 1.05)			
Male: Year 7 follow-up (n=51)	-0.72 (± 1.27)			
Male: Year 8 follow-up (n=40)	-0.74 (± 1.3)			
Male: Year 9 follow-up (n=33)	-1.02 (± 1.08)			
Male: Year 10 follow-up (n=25)	-0.87 (± 1.39)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in HDL cholesterol - Adult population

End point title	Change from baseline in HDL cholesterol - Adult population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: mmol/l				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=127)	0.03 (± 0.41)			
Female: Year 2 follow-up (n=98)	-0.01 (± 0.33)			
Female: Year 3 follow-up (n=79)	0.03 (± 0.46)			
Female: Year 4 follow-up (n=65)	0.03 (± 0.4)			
Female: Year 5 follow-up (n=57)	0.05 (± 0.4)			
Female: Year 6 follow-up (n=46)	-0.06 (± 0.44)			
Female: Year 7 follow-up (n=33)	-0.04 (± 0.5)			
Female: Year 8 follow-up (n=24)	0.04 (± 0.41)			
Female: Year 9 follow-up (n=27)	0.03 (± 0.33)			
Female: Year 10 follow-up (n=18)	0.06 (± 0.27)			
Male: Year 1 follow-up (n=160)	-0.02 (± 0.23)			
Male: Year 2 follow-up (n=139)	-0 (± 0.28)			
Male: Year 3 follow-up (n=101)	0 (± 0.21)			
Male: Year 4 follow-up (n=81)	0.04 (± 0.28)			
Male: Year 5 follow-up (n=67)	0.07 (± 0.21)			
Male: Year 6 follow-up (n=54)	0.08 (± 0.46)			
Male: Year 7 follow-up (n=50)	0.18 (± 0.52)			
Male: Year 8 follow-up (n=34)	0.12 (± 0.43)			
Male: Year 9 follow-up (n=31)	0.14 (± 0.35)			
Male: Year 10 follow-up (n=23)	0.1 (± 0.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in LDL cholesterol - Adult population

End point title	Change from baseline in LDL cholesterol - Adult population
End point description:	
Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.	
End point type	Secondary
End point timeframe:	
Up to 10 years of follow up	

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: mmol/l				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=104)	-0.04 (± 0.9)			
Female: Year 2 follow-up (n=74)	-0.08 (± 1.06)			
Female: Year 3 follow-up (n=54)	-0.01 (± 1.34)			
Female: Year 4 follow-up (n=46)	-0.08 (± 0.86)			
Female: Year 5 follow-up (n=43)	0.05 (± 1.06)			
Female: Year 6 follow-up (n=36)	-0.11 (± 1.19)			
Female: Year 7 follow-up (n=24)	-0.33 (± 1.4)			
Female: Year 8 follow-up (n=15)	0 (± 1.59)			
Female: Year 9 follow-up (n=17)	-0.31 (± 1.48)			
Female: Year 10 follow-up (n=9)	-0.05 (± 1.68)			
Male: Year 1 follow-up (n=120)	-0.28 (± 0.85)			
Male: Year 2 follow-up (n=106)	-0.42 (± 0.85)			
Male: Year 3 follow-up (n=70)	-0.42 (± 0.9)			
Male: Year 4 follow-up (n=51)	-0.37 (± 0.9)			
Male: Year 5 follow-up (n=47)	-0.19 (± 0.82)			
Male: Year 6 follow-up (n=37)	-0.45 (± 0.98)			
Male: Year 7 follow-up (n=31)	-0.34 (± 0.97)			
Male: Year 8 follow-up (n=21)	-0.53 (± 0.74)			
Male: Year 9 follow-up (n=18)	-0.61 (± 0.84)			
Male: Year 10 follow-up (n=9)	-0.63 (± 0.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in triglycerides - Adult population

End point title	Change from baseline in triglycerides - Adult population
End point description:	
Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm.	
End point type	Secondary
End point timeframe:	
Up to 9 years of follow up	

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: mmol/l				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=35)	0.17 (± 1)			
Female: Year 2 follow-up (n=18)	0.04 (± 0.7)			
Female: Year 3 follow-up (n=10)	-0.02 (± 0.66)			
Female: Year 4 follow-up (n=10)	0.2 (± 1.05)			
Female: Year 5 follow-up (n=10)	-0.06 (± 0.93)			
Female: Year 6 follow-up (n=9)	0.09 (± 0.7)			
Female: Year 7 follow-up (n=3)	0.48 (± 2.63)			
Female: Year 8 follow-up (n=1)	1.06 (± 9999.999)			
Male: Year 1 follow-up (n=50)	0.2 (± 0.78)			
Male: Year 2 follow-up (n=40)	0.19 (± 0.74)			
Male: Year 3 follow-up (n=16)	0.02 (± 0.38)			
Male: Year 4 follow-up (n=11)	-0.05 (± 0.6)			
Male: Year 5 follow-up (n=9)	-0.17 (± 0.67)			
Male: Year 6 follow-up (n=6)	-0.41 (± 0.99)			
Male: Year 7 follow-up (n=5)	-0.17 (± 0.74)			
Male: Year 9 follow-up (n=1)	1.7 (± 9999.999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Bone age/Chronological age - Paediatric population

End point title	Change from baseline in Bone age/Chronological age - Paediatric population
End point description:	Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm
End point type	Secondary
End point timeframe:	Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: ratio				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=1250,602,199,31,39,11,3)	0.04 (± 0.12)	0.05 (± 0.13)	0.02 (± 0.14)	0.04 (± 0.09)
Year 2 follow-up (n=975,475,164,16,32,12,4)	0.09 (± 0.14)	0.09 (± 0.15)	0.07 (± 0.15)	0.12 (± 0.17)
Year 3 follow-up (n=774,364,146,14,19,7,3)	0.13 (± 0.15)	0.15 (± 0.17)	0.07 (± 0.15)	0.1 (± 0.12)
Year 4 follow-up (n=518,265,116,8,14,3,5)	0.17 (± 0.17)	0.18 (± 0.17)	0.1 (± 0.17)	0.18 (± 0.2)
Year 5 follow-up (n=406,194,87,6,11,5,5)	0.21 (± 0.18)	0.21 (± 0.18)	0.13 (± 0.18)	0.1 (± 0.26)
Year 6 follow-up (n=244,138,55,4,2,2,1)	0.25 (± 0.33)	0.24 (± 0.18)	0.15 (± 0.19)	0.17 (± 0.45)
Year 7 follow-up (n=172,109,48,3,3,0,1)	0.27 (± 0.37)	0.25 (± 0.23)	0.16 (± 0.19)	0.34 (± 0.18)
Year 8 follow-up (n=123,66,31,0,3,1,2)	0.28 (± 0.42)	0.32 (± 0.18)	0.2 (± 0.17)	9999.999 (± 9999.999)
Year 9 follow-up (n=82,45,15,1,3,2,2)	0.25 (± 0.5)	0.3 (± 0.26)	0.17 (± 0.19)	0.23 (± 9999.999)
Year 10 follow-up (n=29,14,10,1,1,0,1)	0.21 (± 0.8)	0.35 (± 0.22)	0.13 (± 0.34)	0.38 (± 9999.999)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	

Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: ratio				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=1250,602,199,31,39,11,3)	0.02 (± 0.1)	0.01 (± 0.09)	0.1 (± 0.15)	
Year 2 follow-up (n=975,475,164,16,32,12,4)	0.05 (± 0.12)	0.09 (± 0.13)	0.11 (± 0.32)	
Year 3 follow-up (n=774,364,146,14,19,7,3)	0.07 (± 0.14)	0.13 (± 0.15)	0.08 (± 0.28)	
Year 4 follow-up (n=518,265,116,8,14,3,5)	0.03 (± 0.16)	0.16 (± 0.14)	0.21 (± 0.33)	
Year 5 follow-up (n=406,194,87,6,11,5,5)	0.14 (± 0.13)	0.23 (± 0.17)	0.28 (± 0.39)	
Year 6 follow-up (n=244,138,55,4,2,2,1)	0.25 (± 0.11)	0.13 (± 0.05)	0.25 (± 9999.999)	
Year 7 follow-up (n=172,109,48,3,3,0,1)	0.22 (± 0.09)	9999.999 (± 9999.999)	0.15 (± 9999.999)	
Year 8 follow-up (n=123,66,31,0,3,1,2)	0.04 (± 0.08)	0.03 (± 9999.999)	0.29 (± 0.05)	
Year 9 follow-up (n=82,45,15,1,3,2,2)	0.24 (± 0.13)	0.09 (± 0.12)	0.26 (± 0)	
Year 10 follow-up (n=29,14,10,1,1,0,1)	0.18 (± 9999.999)	9999.999 (± 9999.999)	0.27 (± 9999.999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in insulin-like growth factor 1 (IGF-I) SDS (Brabant) - Paediatric population

End point title	Change from baseline in insulin-like growth factor 1 (IGF-I) SDS (Brabant) - Paediatric population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: Standard deviation scores				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=2562,1044,314,30,93,20,16)	2.17 (± 1.62)	1.73 (± 1.41)	2.26 (± 1.45)	2.03 (± 1.69)

Year 2 follow-up (n=2092,826,252,17,67,20,14)	2.42 (± 1.81)	1.78 (± 1.54)	2.28 (± 1.69)	2.32 (± 2.27)
Year 3 follow-up (n=1673,652,235,19,47,11,11)	2.45 (± 1.88)	1.83 (± 1.59)	2.37 (± 1.76)	2.47 (± 2.03)
Year 4 follow-up (n=1248,502,176,9,31,10,11)	2.25 (± 1.9)	1.68 (± 1.7)	2.1 (± 1.81)	2.84 (± 1.82)
Year 5 follow-up (n=881,361,139,7,19,5,7)	2.18 (± 1.92)	1.36 (± 1.9)	1.86 (± 2.1)	1.42 (± 2.12)
Year 6 follow-up (n=634,267,96,5,10,4,3)	1.95 (± 1.93)	1.39 (± 1.76)	1.71 (± 1.69)	2.36 (± 0.99)
Year 7 follow-up (n=428,188,73,4,9,3,2)	1.91 (± 1.8)	1.54 (± 1.68)	1.71 (± 1.83)	1.31 (± 1.22)
Year 8 follow-up (n=285,117,44,2,5,3,1)	1.68 (± 2.01)	1.37 (± 1.69)	1.5 (± 1.83)	1.04 (± 1.73)
Year 9 follow-up (n=204,83,29,3,1,3,2)	1.67 (± 1.78)	1.44 (± 1.76)	1.75 (± 1.4)	2.38 (± 2.27)
Year 10 follow-up (n=108,39,16,3,1,1,2)	1.72 (± 1.8)	1.23 (± 1.53)	1.83 (± 1.47)	2.03 (± 0.54)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: Standard deviation scores				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=2562,1044,314,30,93,20,16)	1.8 (± 1.57)	1.53 (± 1.3)	1.71 (± 1.85)	
Year 2 follow-up (n=2092,826,252,17,67,20,14)	2.18 (± 1.72)	1.79 (± 1.52)	2.1 (± 1.52)	
Year 3 follow-up (n=1673,652,235,19,47,11,11)	2.41 (± 1.95)	1.58 (± 2.23)	1.91 (± 1.78)	
Year 4 follow-up (n=1248,502,176,9,31,10,11)	2.04 (± 2.09)	1.6 (± 1.91)	2.1 (± 1.69)	
Year 5 follow-up (n=881,361,139,7,19,5,7)	2.09 (± 1.75)	0.65 (± 2.15)	1.65 (± 1.94)	
Year 6 follow-up (n=634,267,96,5,10,4,3)	1.12 (± 2.18)	0.99 (± 2.84)	0.52 (± 2.69)	
Year 7 follow-up (n=428,188,73,4,9,3,2)	1.81 (± 1.45)	-2.07 (± 1.31)	-0.32 (± 2.59)	
Year 8 follow-up (n=285,117,44,2,5,3,1)	2.68 (± 2.11)	-0.81 (± 1.03)	-0.45 (± 9999.999)	
Year 9 follow-up (n=204,83,29,3,1,3,2)	3.13 (± 9999.999)	-1.35 (± 1.82)	-0.98 (± 3.47)	
Year 10 follow-up (n=108,39,16,3,1,1,2)	4.16 (± 9999.999)	-1.27 (± 9999.999)	-0.81 (± 4.01)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in insulin-like growth factor binding protein 3 (IGFBP-3) SDS (Juul) - Paediatric population

End point title	Change from baseline in insulin-like growth factor binding protein 3 (IGFBP-3) SDS (Juil) - Paediatric population
End point description:	Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints. The number "9999.999" represents data not applicable for a particular arm
End point type	Secondary
End point timeframe:	Up to 10 years of follow up

End point values	Growth Hormone Deficiency (GHD) - Paediatric Population	Small for Gestational Age (SGA) - Paediatric Population	Turner Syndrome (TS) - Paediatric Population	Chronic Renal Disease (CRD) - Paediatric Population
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7141	3200	936	200
Units: Standard deviation scores				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=1386,589,145,18,45,11,9)	1.4 (± 1.7)	1.33 (± 1.5)	1.43 (± 1.74)	2.04 (± 1.77)
Year 2 follow-up (n=1126,453,119,8,30,7,8)	1.63 (± 1.79)	1.47 (± 1.65)	1.79 (± 1.82)	2.23 (± 1.63)
Year 3 follow-up (n=893,359,117,9,18,5,7)	1.82 (± 1.92)	1.65 (± 1.73)	2.02 (± 1.89)	2.87 (± 3.34)
Year 4 follow-up (n=670,283,80,3,15,2,5)	1.92 (± 1.98)	1.75 (± 1.9)	1.85 (± 2.34)	2.31 (± 2.16)
Year 5 follow-up (n=488,204,66,2,9,2,4)	2.01 (± 1.95)	1.85 (± 2.06)	1.51 (± 2.31)	2.41 (± 0.12)
Year 6 follow-up (n=339,160,44,2,5,1,1)	2.05 (± 2.11)	2.21 (± 1.97)	2 (± 2.01)	2.32 (± 1.53)
Year 7 follow-up (n=210,113,32,3,6,1,0)	2.3 (± 2.16)	2.26 (± 2.18)	1.98 (± 2.09)	2.43 (± 1.67)
Year 8 follow-up (n=140,75,19,2,2,1,0)	1.79 (± 2.22)	2.1 (± 1.96)	1.86 (± 2.62)	1.98 (± 1.63)
Year 9 follow-up (n=91,57,12,1,0,1,0)	2.2 (± 2.19)	2.08 (± 2.03)	1.8 (± 1.96)	3.15 (± 9999.999)
Year 10 follow-up (n=44,28,5,2,0,0,0)	2.43 (± 2.15)	2.1 (± 1.64)	2.69 (± 1.28)	3.14 (± 1.16)

End point values	Idiopathic Short Stature (ISS) - Paediatric Population	Noonan Syndrome (NS) - Paediatric Population	Prader-Willi Syndrome (PWS) - Paediatric Population	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	317	106	67	
Units: Standard deviation scores				
arithmetic mean (standard deviation)				
Year 1 follow-up (n=1386,589,145,18,45,11,9)	1.3 (± 2.19)	1.01 (± 1.42)	2.16 (± 1.24)	
Year 2 follow-up (n=1126,453,119,8,30,7,8)	1.94 (± 1.21)	1.28 (± 1.14)	1.69 (± 1.4)	

Year 3 follow-up (n=893,359,117,9,18,5,7)	1.88 (± 1.53)	2.39 (± 2.78)	2.37 (± 2.29)
Year 4 follow-up (n=670,283,80,3,15,2,5)	1.45 (± 1.3)	1.22 (± 0.91)	2.83 (± 1.4)
Year 5 follow-up (n=488,204,66,2,9,2,4)	1.91 (± 1.51)	1.34 (± 0.81)	3 (± 2.83)
Year 6 follow-up (n=339,160,44,2,5,1,1)	1.16 (± 1.8)	0.32 (± 9999.999)	3.08 (± 9999.999)
Year 7 follow-up (n=210,113,32,3,6,1,0)	2.27 (± 3.01)	0.29 (± 9999.999)	9999.999 (± 9999.999)
Year 8 follow-up (n=140,75,19,2,2,1,0)	1.08 (± 1.94)	0.59 (± 9999.999)	9999.999 (± 9999.999)
Year 9 follow-up (n=91,57,12,1,0,1,0)	9999.999 (± 9999.999)	0.28 (± 9999.999)	9999.999 (± 9999.999)
Year 10 follow-up (n=44,28,5,2,0,0,0)	9999.999 (± 9999.999)	9999.999 (± 9999.999)	9999.999 (± 9999.999)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in BMI - Adult population

End point title	Change from baseline in BMI - Adult population
End point description:	
Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.	
End point type	Secondary
End point timeframe:	
Up to 10 years of follow up	

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: kg/sqm				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=268)	-0.04 (± 3.02)			
Female: Year 2 follow-up (n=206)	0.57 (± 4.89)			
Female: Year 3 follow-up (n=166)	0.6 (± 4.29)			
Female: Year 4 follow-up (n=134)	0.46 (± 2.92)			
Female: Year 5 follow-up (n=112)	0.23 (± 2.72)			
Female: Year 6 follow-up (n=95)	0.18 (± 2.66)			
Female: Year 7 follow-up (n=82)	0.27 (± 3.17)			
Female: Year 8 follow-up (n=62)	0.8 (± 2.9)			
Female: Year 9 follow-up (n=56)	0.4 (± 3.1)			
Female: Year 10 follow-up (n=39)	0.82 (± 3.11)			
Male: Year 1 follow-up (n=310)	0.18 (± 3.21)			

Male: Year 2 follow-up (n=262)	0 (± 2.52)			
Male: Year 3 follow-up (n=193)	0.41 (± 4.53)			
Male: Year 4 follow-up (n=177)	0.31 (± 3.64)			
Male: Year 5 follow-up (n=139)	0.31 (± 3.38)			
Male: Year 6 follow-up (n=120)	0.52 (± 2.95)			
Male: Year 7 follow-up (n=94)	0.32 (± 3.48)			
Male: Year 8 follow-up (n=88)	0.68 (± 3.51)			
Male: Year 9 follow-up (n=63)	0.66 (± 3.53)			
Male: Year 10 follow-up (n=50)	1.07 (± 3.04)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in IGF-I SDS (Brabant) - Adult population

End point title	Change from baseline in IGF-I SDS (Brabant) - Adult population
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End point description:

Analysis was based on the effectiveness analysis set. Here, "n" represents the number of subjects with data available at specified timepoints.

End point type	Secondary
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End point timeframe:

Up to 10 years of follow up

End point values	Adult Growth Hormone Deficiency (AGHD) - Adult Population			
Subject group type	Subject analysis set			
Number of subjects analysed	971			
Units: Standard deviation scores				
arithmetic mean (standard deviation)				
Female: Year 1 follow-up (n=219)	1.2 (± 1.51)			
Female: Year 2 follow-up (n=168)	1.32 (± 1.47)			
Female: Year 3 follow-up (n=133)	1.29 (± 1.4)			
Female: Year 4 follow-up (n=112)	1.52 (± 1.45)			
Female: Year 5 follow-up (n=90)	1.27 (± 1.43)			
Female: Year 6 follow-up (n=69)	1.47 (± 1.56)			
Female: Year 7 follow-up (n=62)	1.8 (± 1.17)			
Female: Year 8 follow-up (n=47)	1.54 (± 1.46)			
Female: Year 9 follow-up (n=41)	1.93 (± 1.44)			
Female: Year 10 follow-up (n=27)	1.46 (± 1.49)			
Male: Year 1 follow-up (n=258)	1.52 (± 1.47)			
Male: Year 2 follow-up (n=218)	1.64 (± 1.46)			
Male: Year 3 follow-up (n=167)	1.51 (± 1.52)			
Male: Year 4 follow-up (n=149)	1.42 (± 1.47)			
Male: Year 5 follow-up (n=107)	1.41 (± 1.55)			

Male: Year 6 follow-up (n=97)	1.54 (± 1.53)			
Male: Year 7 follow-up (n=82)	1.34 (± 1.43)			
Male: Year 8 follow-up (n=71)	1.03 (± 1.49)			
Male: Year 9 follow-up (n=54)	1.48 (± 1.45)			
Male: Year 10 follow-up (n=46)	1.72 (± 1.29)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Full study duration (01 Apr 2006 to 31 Dec 2016)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20
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Reporting groups

Reporting group title	Paediatric GHD
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Reporting group description:

Paediatric patients with Growth Hormone Deficiency who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Paediatric SGA
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Reporting group description:

Paediatric patients with Small for Gestational Age (SGA) who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Paediatric TS
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Reporting group description:

Paediatric patients with Turner Syndrome (TA) who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Paediatric CRD
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Reporting group description:

Paediatric patients with chronic renal disease (CRD) who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Paediatric ISS
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Reporting group description:

Paediatric patients with idiopathic short stature (ISS) who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Paediatric NS
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Reporting group description:

Paediatric patients with Noonan syndrome (NS) who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Paediatric PWS
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Reporting group description:

Paediatric patients with Prader-Willi Syndrome (PWS) who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Paediatric Other
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Reporting group description:

The paediatric population with other growth disorder. The population represents full analysis set.

Reporting group title	Adult GHD
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Reporting group description:

Adult patients with adult growth hormone disease (GHD) who were being treated with Norditropin®. The population represents full analysis set.

Reporting group title	Adult Other
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Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There were no non-serious adverse events with frequency of more than 5% in any sub-group.

Serious adverse events	Paediatric GHD	Paediatric SGA	Paediatric TS
Total subjects affected by serious adverse events			
subjects affected / exposed	174 / 9996 (1.74%)	51 / 4274 (1.19%)	30 / 1374 (2.18%)
number of deaths (all causes)	4	1	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Adenoma benign			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic astrocytoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angiosarcoma metastatic			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Astrocytoma malignant			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Brain neoplasm			
subjects affected / exposed	3 / 9996 (0.03%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burkitt's lymphoma			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choroid plexus carcinoma			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniopharyngioma			
subjects affected / exposed	3 / 9996 (0.03%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniopharyngioma benign			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enchondromatosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicle centre lymphoma, follicular grade I, II, III			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer stage 0			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioneuronal tumour			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic leukaemia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mantle cell lymphoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma recurrent			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple myeloma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal sinus cancer			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	3 / 9996 (0.03%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	3 / 9996 (0.03%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm recurrence			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephroblastoma			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-secretory adenoma of pituitary			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral neoplasm benign			

subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primitive neuroectodermal tumour			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Recurrent cancer			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-cell lymphoma			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenotonsillectomy			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone lesion excision			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystectomy			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystostomy			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear operation			

subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrostomy closure			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip surgery			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb operation			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myringotomy			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchidopexy			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal dialysis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour removal			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plastic surgery to the face			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal transplant			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff repair			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fusion surgery			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus correction			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect repair			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wisdom teeth removal			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pre-eclampsia			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Condition aggravated			
subjects affected / exposed	2 / 9996 (0.02%)	2 / 4274 (0.05%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Discomfort			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease recurrence			
subjects affected / exposed	3 / 9996 (0.03%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	2 / 9996 (0.02%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site atrophy			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	2 / 9996 (0.02%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 9996 (0.03%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian disorder			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicocele			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal disorder			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperventilation			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery wall hypertrophy			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinorrhoea			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			

subjects affected / exposed	1 / 9996 (0.01%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Screaming			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep disorder			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tic			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
alternative dictionary used: MedDRA 3			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	1 / 9996 (0.01%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood glucose decreased			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature fluctuation			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Catheterisation cardiac			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cortisol abnormal			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cortisol decreased			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paracentesis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident at work			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Alcohol poisoning			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			

subjects affected / exposed	0 / 9996 (0.00%)	2 / 4274 (0.05%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greenstick fracture			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open fracture			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt malfunction			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Arnold-Chiari malformation			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicuspid aortic valve			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choanal atresia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital foot malformation			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental glaucoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gonadal dysgenesis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hamartoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interruption of aortic arch			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pectus excavatum			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibial torsion			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type V hyperlipidaemia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 9996 (0.02%)	1 / 4274 (0.02%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem infarction			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral cyst			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral disorder			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous thrombosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	5 / 9996 (0.05%)	2 / 4274 (0.05%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			

subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	8 / 9996 (0.08%)	2 / 4274 (0.05%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	7 / 8	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	2 / 9996 (0.02%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	4 / 9996 (0.04%)	2 / 4274 (0.05%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	4 / 5	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	12 / 9996 (0.12%)	3 / 4274 (0.07%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	1 / 23	0 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 9996 (0.01%)	2 / 4274 (0.05%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal lobe epilepsy			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transverse sinus thrombosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haematoma			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Middle ear disorder			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otorrhoea			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Macular degeneration			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Maculopathy			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular hyperaemia			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	1 / 9996 (0.01%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal prolapse			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell epulis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory bowel disease			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			

subjects affected / exposed	1 / 9996 (0.01%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	5 / 9996 (0.05%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 5	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Night sweats			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash generalised			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin striae			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenocortical insufficiency acute			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune thyroiditis			

subjects affected / exposed	1 / 9996 (0.01%)	2 / 4274 (0.05%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucocorticoid deficiency			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	4 / 9996 (0.04%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	4 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary haemorrhage			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 9996 (0.03%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Collagen disorder			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphysiolysis			
subjects affected / exposed	3 / 9996 (0.03%)	3 / 4274 (0.07%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	2 / 3	3 / 3	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kyphoscoliosis			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle tightness			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	4 / 9996 (0.04%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	3 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	4 / 9996 (0.04%)	1 / 4274 (0.02%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	4 / 4	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			

subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermo-hypodermatitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	4 / 9996 (0.04%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic fever with renal syndrome			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster infection neurological			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 9996 (0.00%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	1 / 9996 (0.01%)	1 / 4274 (0.02%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	7 / 9996 (0.07%)	1 / 4274 (0.02%)	2 / 1374 (0.15%)
occurrences causally related to treatment / all	0 / 8	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperlipidaemia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	2 / 9996 (0.02%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lack of satiety			
subjects affected / exposed	1 / 9996 (0.01%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			

subjects affected / exposed	4 / 9996 (0.04%)	1 / 4274 (0.02%)	1 / 1374 (0.07%)
occurrences causally related to treatment / all	1 / 4	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 9996 (0.02%)	3 / 4274 (0.07%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	1 / 2	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin D deficiency			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Paediatric CRD	Paediatric ISS	Paediatric NS
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 290 (2.41%)	9 / 485 (1.86%)	3 / 154 (1.95%)
number of deaths (all causes)	2	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoma benign			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic astrocytoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angiosarcoma metastatic			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Astrocytoma malignant			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burkitt's lymphoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choroid plexus carcinoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniopharyngioma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniopharyngioma benign			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enchondromatosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicle centre lymphoma, follicular grade I, II, III			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer stage 0			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioneuronal tumour			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic leukaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mantle cell lymphoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma recurrent			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple myeloma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal sinus cancer			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm recurrence			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephroblastoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-secretory adenoma of pituitary			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral neoplasm benign			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primitive neuroectodermal tumour			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Recurrent cancer			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-cell lymphoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenotonsillectomy			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone lesion excision			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystectomy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystostomy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear operation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrostomy closure			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip surgery			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb operation			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myringotomy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchidopexy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal dialysis			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour removal			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plastic surgery to the face			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal transplant			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff repair			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fusion surgery			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus correction			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect repair			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wisdom teeth removal			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pre-eclampsia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Condition aggravated			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Death			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Discomfort			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease recurrence			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site atrophy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian disorder			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicocele			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Adenoidal disorder			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperventilation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery wall hypertrophy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinorrhoea			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Screaming			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep disorder			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tic			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
alternative dictionary used: MedDRA 3			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperbilirubinaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood glucose decreased			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature fluctuation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheterisation cardiac			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cortisol abnormal			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cortisol decreased			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paracentesis			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident at work			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greenstick fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt malfunction			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Arnold-Chiari malformation			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicuspid aortic valve			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choanal atresia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital foot malformation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental glaucoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gonadal dysgenesis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hamartoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interruption of aortic arch			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pectus excavatum			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibial torsion			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type V hyperlipidaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Brain stem infarction			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral cyst			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral disorder			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous thrombosis			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Epilepsy			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 290 (0.34%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal lobe epilepsy			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transverse sinus thrombosis			

subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haematoma			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Middle ear disorder			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otorrhoea			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Macular degeneration			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Maculopathy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular hyperaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal prolapse			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell epulis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory bowel disease			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Night sweats			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash generalised			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin striae			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenocortical insufficiency acute			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune thyroiditis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucocorticoid deficiency			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary haemorrhage			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Collagen disorder			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphysiolysis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kyphoscoliosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle tightness			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 290 (0.00%)	2 / 485 (0.41%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	1 / 154 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermo-hypodermatitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	1 / 290 (0.34%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic fever with renal syndrome			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster infection neurological			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 290 (0.00%)	1 / 485 (0.21%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinusitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperlipidaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lack of satiety			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin D deficiency			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Paediatric PWS	Paediatric Other	Adult GHD
Total subjects affected by serious			

adverse events			
subjects affected / exposed	11 / 132 (8.33%)	18 / 1035 (1.74%)	133 / 2321 (5.73%)
number of deaths (all causes)	1	3	14
number of deaths resulting from adverse events	0	0	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenoma benign			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaplastic astrocytoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Angiosarcoma metastatic			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Astrocytoma malignant			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Benign neoplasm			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder neoplasm			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain neoplasm			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchial carcinoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Burkitt's lymphoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choroid plexus carcinoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer metastatic			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Craniopharyngioma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniopharyngioma benign			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enchondromatosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicle centre lymphoma, follicular grade I, II, III			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric cancer stage 0			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioma			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glioneuronal tumour			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemangioma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic leukaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Mantle cell lymphoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medulloblastoma recurrent			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Metastases to meninges			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to spine			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple myeloma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelofibrosis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal sinus cancer			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm malignant			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	9 / 2321 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 11
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Neoplasm progression			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm recurrence			
subjects affected / exposed	0 / 132 (0.00%)	2 / 1035 (0.19%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nephroblastoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-secretory adenoma of pituitary			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral neoplasm benign			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary renal cell carcinoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Papillary thyroid cancer			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour benign			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Primitive neuroectodermal tumour			
subjects affected / exposed	0 / 132 (0.00%)	2 / 1035 (0.19%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Recurrent cancer			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cancer			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Schwannoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
T-cell lymphoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypertension			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shock			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis limb			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenotonsillectomy			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone lesion excision			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystectomy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystostomy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear operation			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrostomy closure			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip surgery			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hospitalisation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb operation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myringotomy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchidopexy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritoneal dialysis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary tumour removal			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plastic surgery to the face			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal transplant			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff repair			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fusion surgery			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus correction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular septal defect repair			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wisdom teeth removal			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Pre-eclampsia			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Condition aggravated			
subjects affected / exposed	2 / 132 (1.52%)	1 / 1035 (0.10%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Death			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	4 / 2321 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 4
Discomfort			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disease recurrence			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face oedema			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperthermia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injection site atrophy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			

subjects affected / exposed	1 / 132 (0.76%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicocele			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	1 / 132 (0.76%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphonia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hyperventilation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oropharyngeal pain			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery wall hypertrophy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinorrhoea			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 132 (0.76%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stridor			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Completed suicide			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Depression			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Restlessness			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Screaming			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sleep disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stress			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tic			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device malfunction			
alternative dictionary used: MedDRA 3			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatorenal syndrome			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood glucose decreased			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Body temperature fluctuation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Catheterisation cardiac			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cortisol abnormal			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cortisol decreased			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paracentesis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Accident at work			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Alcohol poisoning			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Animal bite			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Greenstick fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laceration			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meniscus injury			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shunt malfunction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal compression fracture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon rupture			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Arnold-Chiari malformation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bicuspid aortic valve			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Choanal atresia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital foot malformation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cryptorchism			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Developmental glaucoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gonadal dysgenesis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hamartoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydrocele			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interruption of aortic arch			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pectus excavatum			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Phimosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibial torsion			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type V hyperlipidaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	6 / 2321 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	5 / 2321 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiac failure congestive			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain stem infarction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carpal tunnel syndrome			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral cyst			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral disorder			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral haemorrhage			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral venous thrombosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrospinal fluid leakage			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	4 / 2321 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Convulsion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depressed level of consciousness			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paralysis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial paresis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Generalised tonic-clonic seizure			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemic seizure			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotonia			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Idiopathic intracranial hypertension			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Loss of consciousness			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Optic neuritis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Petit mal epilepsy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			

subjects affected / exposed	2 / 132 (1.52%)	1 / 1035 (0.10%)	5 / 2321 (0.22%)
occurrences causally related to treatment / all	0 / 2	0 / 1	2 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	5 / 2321 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal lobe epilepsy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transverse sinus thrombosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic haematoma			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Middle ear disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otorrhoea			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vertigo			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Macular degeneration			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Maculopathy			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ocular hyperaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retinal detachment			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Strabismus			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Visual impairment			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain lower			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal prolapse			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coeliac disease			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer perforation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Giant cell epulis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammatory bowel disease			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Night sweats			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash generalised			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin striae			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swelling face			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephropathy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prerenal failure			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal impairment			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral stenosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenocortical insufficiency acute			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune thyroiditis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glucocorticoid deficiency			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pituitary haemorrhage			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid mass			
subjects affected / exposed	0 / 132 (0.00%)	2 / 1035 (0.19%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 132 (0.76%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis reactive			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chondromalacia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Collagen disorder			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epiphysiolysis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exostosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibromyalgia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	4 / 2321 (0.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint instability			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kyphoscoliosis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar spinal stenosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle tightness			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteochondrosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoriatic arthropathy			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scoliosis			
subjects affected / exposed	5 / 132 (3.79%)	1 / 1035 (0.10%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	1 / 5	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal column stenosis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis orbital			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic sinusitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermo-hypodermatitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic fever with renal syndrome			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster infection neurological			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster meningitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis pneumococcal			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis chronic			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sinusitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetes mellitus			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 132 (0.00%)	2 / 1035 (0.19%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			

subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperlipidaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	1 / 2321 (0.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lack of satiety			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic alkalosis			
subjects affected / exposed	0 / 132 (0.00%)	1 / 1035 (0.10%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			

subjects affected / exposed	1 / 132 (0.76%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 132 (0.76%)	0 / 1035 (0.00%)	3 / 2321 (0.13%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin B12 deficiency			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin D deficiency			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	2 / 2321 (0.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adult	Other		
Total subjects affected by serious adverse events				
subjects affected / exposed	10 / 163 (6.13%)			
number of deaths (all causes)	0			
number of deaths resulting from adverse events	0			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Acute myeloid leukaemia				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Adenoma benign				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaplastic astrocytoma				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Angiosarcoma metastatic				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Astrocytoma malignant				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Benign neoplasm				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bladder neoplasm				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain neoplasm				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchial carcinoma				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Burkitt's lymphoma				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Choroid plexus carcinoma				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colon cancer metastatic				

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniopharyngioma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Craniopharyngioma benign			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enchondromatosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Follicle centre lymphoma, follicular grade I, II, III			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric cancer stage 0			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glioma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glioneuronal tumour			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemangioma			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intraductal papillary mucinous neoplasm			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lipoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphocytic leukaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mantle cell lymphoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Medulloblastoma recurrent			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to meninges			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to spine			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple myeloma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myelofibrosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nasal sinus cancer			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm malignant			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Neoplasm progression			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm recurrence			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephroblastoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-secretory adenoma of pituitary			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral neoplasm benign			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papillary renal cell carcinoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Papillary thyroid cancer			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pituitary tumour			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pituitary tumour benign			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Primitive neuroectodermal tumour			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Recurrent cancer			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cancer			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal cell carcinoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Schwannoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
T-cell lymphoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			

subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haemorrhage			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotension			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shock			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Venous thrombosis limb			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Adenoidectomy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Adenotonsillectomy			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone lesion excision			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystectomy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystostomy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear operation			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrostomy closure			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip surgery			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hospitalisation			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb operation			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myringotomy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orchidopexy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritoneal dialysis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pituitary tumour removal			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plastic surgery to the face			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal transplant			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rotator cuff repair			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal fusion surgery			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Strabismus correction			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ventricular septal defect repair			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wisdom teeth removal			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Pre-eclampsia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Condition aggravated			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Death				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Discomfort				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disease recurrence				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face oedema				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperthermia				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injection site atrophy				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaise				

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oedema			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral swelling			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sudden death			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian disorder			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Varicocele			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Adenoidal disorder				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthma				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphonia				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperventilation				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oropharyngeal pain				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 163 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary artery wall hypertrophy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhinorrhoea			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sleep apnoea syndrome			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stridor			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillar hypertrophy			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Completed suicide			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mental disorder			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Restlessness			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Screaming			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sleep disorder			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stress			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tic			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Product issues			
Device malfunction			
alternative dictionary used: MedDRA 3			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatorenal syndrome			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Hyperbilirubinaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Liver disorder			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood glucose decreased			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Body temperature fluctuation			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Catheterisation cardiac			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cortisol abnormal			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cortisol decreased			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glycosylated haemoglobin increased			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paracentesis			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Weight decreased			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Accident at work			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Alcohol poisoning			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Animal bite			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carbon monoxide poisoning			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Clavicle fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fall			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fracture			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Greenstick fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hand fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Humerus fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint dislocation			

subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Laceration			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Limb injury			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lower limb fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meniscus injury			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Open fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural complication			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Post procedural haemorrhage			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Radius fracture			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Shunt malfunction			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal compression fracture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stab wound			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thermal burn			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Arnold-Chiari malformation			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bicuspid aortic valve			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Choanal atresia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital foot malformation			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cryptorchism			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Developmental glaucoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gonadal dysgenesis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hamartoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hydrocele			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Interruption of aortic arch			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pectus excavatum			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Phimosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibial torsion			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type V hyperlipidaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac failure			

subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac failure congestive			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardio-respiratory arrest			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiogenic shock			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocarditis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular extrasystoles			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Supraventricular tachycardia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tachycardia			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aphasia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ataxia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain oedema			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Brain stem infarction			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Carpal tunnel syndrome			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral cyst			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral disorder			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral haemorrhage			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral infarction			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral venous thrombosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrospinal fluid leakage			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular accident			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Convulsion			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depressed level of consciousness			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epilepsy			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial paralysis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial paresis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Generalised tonic-clonic seizure			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Headache			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemic seizure			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypotonia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Idiopathic intracranial hypertension			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intracranial pressure increased			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ischaemic stroke			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Loss of consciousness			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Migraine			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple sclerosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Optic neuritis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraesthesia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Partial seizures			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Petit mal epilepsy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sciatica			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Temporal lobe epilepsy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transverse sinus thrombosis			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Bone marrow failure			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sickle cell anaemia with crisis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic haematoma			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Deafness neurosensory			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Middle ear disorder			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otorrhoea			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Macular degeneration			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Maculopathy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ocular hyperaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Retinal detachment			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Strabismus			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Visual impairment			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain lower			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anal prolapse			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Coeliac disease			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			

subjects affected / exposed	2 / 163 (1.23%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer perforation			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Giant cell epulis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileus			
subjects affected / exposed	2 / 163 (1.23%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Inflammatory bowel disease			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Large intestine perforation			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nausea			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Stomatitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Night sweats			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pruritus			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash generalised			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin striae			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Swelling face			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Glycosuria			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephropathy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prerenal failure			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal failure			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urethral stenosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Adrenocortical insufficiency acute			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Autoimmune thyroiditis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Glucocorticoid deficiency			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothyroidism			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pituitary haemorrhage			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thyroid mass			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthritis reactive			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone pain			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chondromalacia			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Collagen disorder			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Epiphysiolysis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Exostosis			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fibromyalgia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intervertebral disc protrusion			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Joint instability			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Kyphoscoliosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbar spinal stenosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Muscle tightness			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal stiffness			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myalgia			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Osteochondrosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteonecrosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pain in extremity			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psoriatic arthropathy			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Scoliosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Spinal column stenosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cellulitis orbital			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic sinusitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Chronic tonsillitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dermo-hypodermatitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Encephalitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Endocarditis			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis norovirus			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal infection			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemorrhagic fever with renal syndrome			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis C			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster infection neurological			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Herpes zoster meningitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infection			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis pneumococcal			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Orchitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Osteomyelitis chronic			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pilonidal cyst			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumonia influenzal			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rhinitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheobronchitis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperglycaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyperlipidaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypernatraemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			

subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lack of satiety			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic alkalosis			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Vitamin B12 deficiency			
subjects affected / exposed	1 / 163 (0.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vitamin D deficiency			
subjects affected / exposed	0 / 163 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Paediatric GHD	Paediatric SGA	Paediatric TS
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 9996 (0.00%)	0 / 4274 (0.00%)	0 / 1374 (0.00%)

Non-serious adverse events	Paediatric CRD	Paediatric ISS	Paediatric NS
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 290 (0.00%)	0 / 485 (0.00%)	0 / 154 (0.00%)

Non-serious adverse events	Paediatric PWS	Paediatric Other	Adult GHD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 132 (0.00%)	0 / 1035 (0.00%)	0 / 2321 (0.00%)

Non-serious adverse events	Adult Other		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 163 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 July 2008	1. The International Outcome Study becomes a part of the Novo Nordisk IMPACT system with the number: GHLiquid-3676. 2. Changes in the content of methodology section to clarify the information on parameters based on specificities of different patient populations and different diagnosis. 3. A new subsections "Visit Procedures/Core parameters" and "Bone age assessment" were added. 4. The section "Adverse events and pregnancies reporting" was updated.
15 June 2009	1. Addition of quality of life assessment in adult population. 2. Addition of medical events of special interest for safety assessment. 3. In the "Baseline" and Follow-up" part, the QoL was added and Resistance, Lean tissue and Fat tissue measurements are deleted. In addition, the "End of GH treatment/De-registration/Change of clinic" part was deleted. 4. Changes to Ethical considerations section for more clarification.
12 May 2011	1. Study timelines was updated to reflect a 5-year extension of recruitment period. 2. Study objective section was updated to provide more clarity about Norditropin® efficacy according to different patient groups. 3. The study sample size was updated in line with a 5-year extension of recruitment period. 4. The former subsection Visit procedure/Core parameters was replaced with the subsection Visit procedures. 5. Bone age assessment: the section was updated to reflect reporting of Bone Health Index value in the Nordinet section related to the BoneXpert®. 6. Data management: The content was updated to include requirement for written consent for off-treatment data collection. 7. Sub-section "validation of data": The content was updated in accordance with Nordinet® system advancement. 8. The section "Adverse events" was renamed as Safety reporting. 9. A new section was added: severity assessment definitions. 10. Specified that the reporting of pregnancy in female partner was done if accepted by IEC. 11. Ethical consideration: This section was updated in relation to informed consent for off-treatment data collection in GHD transition phase, pregnancy in female partners and in patients after achieving 18 years.
30 September 2013	1. The subsection "timelines" was updated to implement a Quality Assurance Report. 2. Information on the sample size was updated to reflect the current status of the study. 3. Serious adverse events section was updated to integrate important medical events in the definition of a serious adverse event. 4. The definition of adverse drug reactions(ADRs)/serious adverse drug reactions was clarified. 5. Changes in the section- Identification of AE/ADR: The section was updated to reflect the Novo Nordisk SOP "Handling of Adverse Events and Other Safety Information" (edition 17) and the new EMA Legislation. 6. Changes in the section - Supervision Activities: The section was added to implement supervision activities as described in the Novo Nordisk SOP "Planning, Conduct and Reporting of Non-interventional Studies" (edition 5).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported