Clinical trial results:
A Phase I/II, Multicenter, Open-Label, Noncomparative Study of the International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Group to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiretroviral Activity of Raltegravir (Isentress™, MK-0518) in HIV-1 Infected Children and Adolescents

Summary

EudraCT number	2009-015884-15
Trial protocol	Outside EU/EEA
Global end of trial date	17 May 2017

Results information

Result version number	v1 (current)
This version publication date	25 November 2017
First version publication date	25 November 2017

Trial information

Trial identification

Sponsor protocol code	0518-022

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00485264
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, NJ, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000279-PIP01-08
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 May 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate in infants, children and adolescents the following: 1) the short term safety and tolerability of raltegravir; 2) the steady state plasma concentration profiles and pharmacokinetic parameters of raltegravir; 3) in chronic dosing, to evaluate the safety and tolerability of raltegravir at a selected dose in combination with optimized background therapy (OBT).

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy:

For Cohorts I, IIA, IIB and III stable background Highly Active Antiretroviral Therapy (HAART) is defined as unchanged therapeutic regimen for at least 12 weeks, or treatment experienced (not including therapy to interrupt maternal-infant transmission) but on no treatment for ≥ 4 weeks prior to entry. For Cohort IV, a participant must have received therapy to either interrupt maternal-infant transmission and/or to treat HIV infection. For Cohort V, the participant must have received therapy to interrupt maternal-infant transmission, but have not received other anti-HIV therapies.

Evidence for comparator: -

Actual start date of recruitment	11 September 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	4 Years
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 1
Country: Number of subjects enrolled	Botswana: 3
Country: Number of subjects enrolled	Brazil: 12
Country: Number of subjects enrolled	South Africa: 27
Country: Number of subjects enrolled	United States: 110
Worldwide total number of subjects	153
EEA total number of subjects	0

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	27
Children (2-11 years)	55
Adolescents (12-17 years)	60
Adults (18-64 years)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Children and adolescents ages ≥ 4 weeks to <19 years that were infected with HIV-1 were enrolled in this study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID

Arm description:

Participants ≥ 12 to <19 years of age who received a weight based dose of 200 mg to 600 mg raltegravir poloxamer film coated (PFC) tablets twice daily (BID). After dose selection all participants received 400 mg raltegravir PFC BID.

Arm type	Experimental
Investigational medicinal product name	Raltegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Weight based dose of 200 to 600 mg raltegravir PFC BID. After dose selection, all participants received 400 mg raltegravir PFC BID.

Arm title	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID

Arm description:

Participants ≥ 6 to <12 years of age who received a weight based dose of 200 mg to 400 mg raltegravir PFC tablets BID. After dose selection all participants >=25 kg received 400 mg raltegravir PFC BID.

Arm type	Experimental
Investigational medicinal product name	Raltegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Weight based dose of 200 to 400 mg raltegravir PFC BID. After dose selection, all participants >=25 kg received 400 mg raltegravir PFC BID. Participants <25 kg received a weight based dose of the raltegravir CH BID.

Arm title	Cohort IIB: ~ 6-8 mg/kg Raltegravir CH tablets BID

Arm description:

Participants ≥ 6 to <12 years of age who received a weight based dose of ~6 mg to 8 mg/kg raltegravir chewable (CH) tablets BID. After dose selection all participants received a weight based dose of ~6 mg/kg raltegravir CH BID.

Arm type	Experimental

Investigational medicinal product name	Raltegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

Weight based dose of ~6 mg to 8 mg/kg raltegravir CH tablets BID. After dose selection all participants received a weight based dose of ~6 mg/kg raltegravir CH BID.

Arm title	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID

Arm description:

Participants ≥ 2 to <6 years of age who received a weight based dose of ~6 mg/kg raltegravir CH tablets BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Arm type	Experimental
Investigational medicinal product name	Raltegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable tablet
Routes of administration	Oral use

Dosage and administration details:

Weight based dose of ~6 mg/kg raltegravir CH tablets BID.

Arm title	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID

Arm description:

Participants ≥ 6 months to <2 years of age who received a weight based dose of ~6 mg/kg raltegravir oral granules for suspension (OGS) BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Arm type	Experimental
Investigational medicinal product name	Raltegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Granules
Routes of administration	Oral use

Dosage and administration details:

Weight based dose of ~6 mg/kg raltegravir OGS BID.

Arm title	Cohort V: ~ 6 mg/kg Raltegravir OGS BID

Arm description:

Participants ≥ 4 weeks to <6 months of age who received a weight based dose of ~6 mg/kg raltegravir OGS BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Arm type	Experimental
Investigational medicinal product name	Raltegravir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Granules
Routes of administration	Oral use

Dosage and administration details:

Weight based dose of ~6 mg/kg raltegravir OGS BID.

Number of subjects in period 1	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6-8 mg/kg Raltegravir CH tablets BID
Started	71	16	18
Completed	48	12	17
Not completed	23	4	1
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	4	1	-
Met study objective	-	1	-
Unable to contact	3	1	1
Not Treated	-	-	-
Unknown	1	-	-
Cannot get to clinic	6	-	-
Unwilling to follow requirements	8	1	-
Study site closed	-	-	-

Number of subjects in period 1	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Started	21	15	12
Completed	19	10	6
Not completed	2	5	6
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	-	1	-
Met study objective	1	-	-
Unable to contact	-	-	-
Not Treated	-	1	-
Unknown	-	-	-
Cannot get to clinic	1	1	2
Unwilling to follow requirements	-	1	-
Study site closed	-	-	4

Baseline characteristics

Reporting groups	
Reporting group title	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID
Reporting group description:	
Participants ≥ 12 to <19 years of age who received a weight based dose of 200 mg to 600 mg raltegravir poloxamer film coated (PFC) tablets twice daily (BID). After dose selection all participants received 400 mg raltegravir PFC BID.	
Reporting group title	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID
Reporting group description:	
Participants ≥ 6 to <12 years of age who received a weight based dose of 200 mg to 400 mg raltegravir PFC tablets BID. After dose selection all participants >=25 kg received 400 mg raltegravir PFC BID.	
Reporting group title	Cohort IIB: ~ 6-8 mg/kg Raltegravir CH tablets BID
Reporting group description:	
Participants ≥ 6 to <12 years of age who received a weight based dose of ~6 mg to 8 mg/kg raltegravir chewable (CH) tablets BID. After dose selection all participants received a weight based dose of ~6 mg/kg raltegravir CH BID.	
Reporting group title	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Reporting group description:	
Participants ≥ 2 to <6 years of age who received a weight based dose of ~6 mg/kg raltegravir CH tablets BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.	
Reporting group title	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID
Reporting group description:	
Participants ≥ 6 months to <2 years of age who received a weight based dose of ~6 mg/kg raltegravir oral granules for suspension (OGS) BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.	
Reporting group title	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Reporting group description:	
Participants ≥ 4 weeks to <6 months of age who received a weight based dose of ~6 mg/kg raltegravir OGS BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.	

Reporting group values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6-8 mg/kg Raltegravir CH tablets BID
Number of subjects	71	16	18
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	16	18
Adolescents (12-17 years)	60	0	0
Adults (18-64 years)	11	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	15	9.1	8.9
standard deviation	± 2.0	± 1.6	± 1.6

Gender Categorical Units: Subjects			
Female	34	7	7
Male	37	9	11
Age Continuous Units: Years			
arithmetic mean			
standard deviation	±	±	±

Reporting group values	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Number of subjects	21	15	12
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	15	12
Children (2-11 years)	21	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	3.1	1.0	0.3
standard deviation	± 1.2	± 0.5	± 0.1
Gender Categorical Units: Subjects			
Female	13	5	4
Male	8	10	8
Age Continuous Units: Years			
arithmetic mean			
standard deviation	±	±	±

Reporting group values	Total		
Number of subjects	153		
Age Categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	27		
Children (2-11 years)	55		
Adolescents (12-17 years)	60		
Adults (18-64 years)	11		
From 65-84 years	0		
85 years and over	0		

Age Continuous Units: years arithmetic mean standard deviation	- 		
Gender Categorical Units: Subjects			
Female Male	70 83		
Age Continuous Units: Years arithmetic mean standard deviation	- 		

Subject analysis sets

Subject analysis set title	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 12 to <19 years of age who received a weight based dose of 200 mg to 600 mg raltegravir poloxamer film coated (PFC) tablets twice daily (BID). After dose selection all participants received 400 mg raltegravir PFC BID.

Subject analysis set title	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 6 to <12 years of age who received a weight based dose of 200 mg to 400 mg raltegravir PFC tablets BID. After dose selection all participants >=25 kg received 400 mg raltegravir PFC BID.

Subject analysis set title	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 6 to <12 years of age who received a weight based dose of ~6 mg to 8 mg/kg raltegravir chewable (CH) tablets BID. After dose selection all participants received a weight based dose of ~6 mg/kg raltegravir CH BID.

Subject analysis set title	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 2 to <6 years of age who received a weight based dose of ~6 mg/kg raltegravir CH tablets BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Subject analysis set title	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 6 months to <2 years of age who received a weight based dose of ~6 mg/kg raltegravir oral granules for suspension (OGS) BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Subject analysis set title	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 4 weeks to <6 months of age who received a weight based dose of ~6 mg/kg raltegravir OGS BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Reporting group values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID
Number of subjects	71	16	18

Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	16	18
Adolescents (12-17 years)	60	0	0
Adults (18-64 years)	11	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years arithmetic mean standard deviation	±	±	±
Gender Categorical Units: Subjects			
Female	34	7	7
Male	37	9	11
Age Continuous Units: Years arithmetic mean	15	9.1	8.9
standard deviation	± 2	± 1.6	± 1.6

Reporting group values	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Number of subjects	21	14	12
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	15	12
Children (2-11 years)	21	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: years arithmetic mean standard deviation	±	±	±
Gender Categorical Units: Subjects			
Female	13	5	4
Male	8	9	8

Age Continuous Units: Years			
arithmetic mean	3.1	1.0	0.3
standard deviation	± 1.2	± 0.5	± 0.1

End points

End points reporting groups

Reporting group title	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID
Reporting group description:	
Participants ≥ 12 to <19 years of age who received a weight based dose of 200 mg to 600 mg raltegravir poloxamer film coated (PFC) tablets twice daily (BID). After dose selection all participants received 400 mg raltegravir PFC BID.	
Reporting group title	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID
Reporting group description:	
Participants ≥ 6 to <12 years of age who received a weight based dose of 200 mg to 400 mg raltegravir PFC tablets BID. After dose selection all participants >=25 kg received 400 mg raltegravir PFC BID.	
Reporting group title	Cohort IIB: ~ 6-8 mg/kg Raltegravir CH tablets BID
Reporting group description:	
Participants ≥ 6 to <12 years of age who received a weight based dose of ~6 mg to 8 mg/kg raltegravir chewable (CH) tablets BID. After dose selection all participants received a weight based dose of ~6 mg/kg raltegravir CH BID.	
Reporting group title	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Reporting group description:	
Participants ≥ 2 to <6 years of age who received a weight based dose of ~6 mg/kg raltegravir CH tablets BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.	
Reporting group title	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID
Reporting group description:	
Participants ≥ 6 months to <2 years of age who received a weight based dose of ~6 mg/kg raltegravir oral granules for suspension (OGS) BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.	
Reporting group title	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Reporting group description:	
Participants ≥ 4 weeks to <6 months of age who received a weight based dose of ~6 mg/kg raltegravir OGS BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.	
Subject analysis set title	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants ≥ 12 to <19 years of age who received a weight based dose of 200 mg to 600 mg raltegravir poloxamer film coated (PFC) tablets twice daily (BID). After dose selection all participants received 400 mg raltegravir PFC BID.	
Subject analysis set title	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants ≥ 6 to <12 years of age who received a weight based dose of 200 mg to 400 mg raltegravir PFC tablets BID. After dose selection all participants >=25 kg received 400 mg raltegravir PFC BID.	
Subject analysis set title	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants ≥ 6 to <12 years of age who received a weight based dose of ~6 mg to 8 mg/kg raltegravir chewable (CH) tablets BID. After dose selection all participants received a weight based dose of ~6 mg/kg raltegravir CH BID.	
Subject analysis set title	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants ≥ 2 to <6 years of age who received a weight based dose of ~6 mg/kg raltegravir CH tablets BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.	
Subject analysis set title	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 6 months to <2 years of age who received a weight based dose of ~6 mg/kg raltegravir oral granules for suspension (OGS) BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Subject analysis set title	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants ≥ 4 weeks to <6 months of age who received a weight based dose of ~6 mg/kg raltegravir OGS BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Primary: Number of participants with one or more adverse events (AEs)

End point title	Number of participants with one or more adverse events

End point description:

An AE is any untoward medical occurrence in a participant administered a study agent and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. The population analyzed was all participants who received at least one dose of raltegravir.

End point type	Primary

End point timeframe:

Up to week 269

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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint.

End point values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	71	16	18	21
Units: Participants				
number (not applicable)	69	16	18	21

End point values	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	12		
Units: Participants				
number (not applicable)	14	12		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants who discontinued study medication due to an AE

End point title	Number of participants who discontinued study medication due to an AE[2]

End point description:

An AE is any untoward medical occurrence in a participant administered a study agent and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. The population analyzed was all participants who received at least one dose of raltegravir.

End point type	Primary

End point timeframe:

Up to week 269

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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint

End point values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	71	16	18	21
Units: Participants				
number (not applicable)	0	0	0	0

End point values	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14	12		
Units: Participants				
number (not applicable)	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Area under the concentration-time curve from time 0-12 hours post-dose for plasma raltegravir (AUC0-12h)

End point title	Area under the concentration-time curve from time 0-12 hours post-dose for plasma raltegravir (AUC0-12h)[3]

End point description:

Blood samples were collected for intensive pharmacokinetics (PK) between Days 5 and 12 following the initial raltegravir dose. If repeat intensive PK was required, it was collected between Days 7 and 14 following the raltegravir dose adjustment. The raltegravir AUC0-12 was determined using non-compartmental analysis.

End point type	Primary

End point timeframe:

Cohorts I, IIA, IIB and III: pre-dose, 0.5, 1, 2, 3, 4, 6, 8 and 12 hours post dose; Cohort IV: pre-dose,

0.5, 1, 2, 4 and 12 hours post dosing; Cohort V: pre-dose, 0.5, 1, 3-5, and 8-10 hours post dosing.

Notes:

[3] - 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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint

End point values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	11	10	12
Units: µM*hr				
geometric mean (geometric coefficient of variation)	15.71 (± 98)	15.84 (± 120)	22.58 (± 34)	17.95 (± 59)

End point values	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	11		
Units: µM*hr				
geometric mean (geometric coefficient of variation)	19.8 (± 34.3)	22.3 (± 40.2)		

Statistical analyses

No statistical analyses for this end point

Primary: Maximum concentration of plasma raltegravir (Cmax)

End point title	Maximum concentration of plasma raltegravir (Cmax)[4]

End point description:

Blood samples were collected for intensive PK between Days 5 and 12 following the initial raltegravir dose. If repeat intensive PK was required, it was collected between Days 7 and 14 following the raltegravir dose adjustment. The raltegravir Cmax was determined using non-compartmental analysis.

End point type	Primary

End point timeframe:

Cohorts I, IIA, IIB and III: pre-dose, 0.5, 1, 2, 3, 4, 6, 8 and 12 hours post dose; Cohort IV: pre-dose, 0.5, 1, 2, 4 and 12 hours post dosing; Cohort V: pre-dose, 0.5, 1, 3-5, and 8-10 hours post dosing.

Notes:

[4] - 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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint

End point values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	11	10	12
Units: µM				
geometric mean (geometric coefficient of variation)	4.00 (± 95)	4.80 (± 130)	10.49 (± 53)	9.74 (± 57)

End point values	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	11		
Units: µM				
geometric mean (geometric coefficient of variation)	10.6 (± 64.8)	8.6 (± 38.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Time to maximum concentration of plasma raltegravir (Tmax)

End point title	Time to maximum concentration of plasma raltegravir

End point description:

Blood samples were collected for intensive PK between Days 5 and 12 following the initial raltegravir dose. If repeat intensive PK was required, it was collected between Days 7 and 14 following the raltegravir dose adjustment. The raltegravir Tmax was determined using non-compartmental analysis.

End point type	Primary

End point timeframe:

Cohorts I, IIA, IIB and III: pre-dose, 0.5, 1, 2, 3, 4, 6, 8 and 12 hours post dose; Cohort IV: pre-dose, 0.5, 1, 2, 4 and 12 hours post dosing; Cohort V: pre-dose, 0.5, 1, 3-5, and 8-10 hours post dosing.

Notes:

[5] - 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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint

End point values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	11	10	12
Units: hr				
arithmetic mean (standard deviation)	1.8 (± 1.8)	2.3 (± 0.9)	0.7 (± 0.2)	1.5 (± 1.3)

End point values	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	11		
Units: hr				
arithmetic mean (standard deviation)	0.82 (± 0.53)	0.88 (± 0.33)		

Statistical analyses

No statistical analyses for this end point

Primary: Concentration at 12 hours post-dose of plasma raltegravir (C12hr)

End point title	Concentration at 12 hours post-dose of plasma raltegravir (C12hr)[6]

End point description:

Blood samples were collected for intensive PK between Days 5 and 12 following the initial raltegravir dose. If repeat intensive PK was required, it was collected between Days 7 and 14 following the raltegravir dose adjustment. The raltegravir C12hr was determined using non-compartmental analysis.

End point type	Primary

End point timeframe:

12 hours post dose

Notes:

[6] - 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: Statistical comparisons between treatment groups were neither planned nor performed for this primary endpoint

End point values	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	11	10	12
Units: nM				
geometric mean (geometric coefficient of variation)	333 (± 78)	246 (± 221)	130 (± 88)	71 (± 55)

End point values	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	11		
Units: nM				
geometric mean (geometric coefficient of variation)	108.2 (± 52.3)	116.6 (± 67.7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to week 269

Adverse event reporting additional description:

All participants who received at least one dose of raltegravir

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20

Reporting groups

Reporting group title	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID

Reporting group description:

Participants ≥ 12 to <19 years of age who received a weight based dose of 200 mg to 600 mg raltegravir PFC) tablets BID. After dose selection all participants received 400 mg raltegravir PFC BID.

Reporting group title	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID

Reporting group description:

Participants ≥ 6 to <12 years of age who received a weight based dose of 200 mg to 400 mg raltegravir PFC tablets BID. After dose selection all participants >=25 kg received 400 mg raltegravir PFC BID.

Reporting group title	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID

Reporting group description:

Participants ≥ 6 to <12 years of age who received a weight based dose of ~6 mg to 8 mg/kg raltegravir chewable (CH) tablets BID. After dose selection all participants received a weight based dose of ~6 mg/kg raltegravir CH BID.

Reporting group title	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID

Reporting group description:

Participants ≥ 2 to <6 years of age who received a weight based dose of ~6 mg/kg raltegravir CH tablets BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Reporting group title	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID

Reporting group description:

Participants ≥ 6 months to <2 years of age who received a weight based dose of ~6 mg/kg raltegravir oral granules for suspension (OGS) BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Reporting group title	Cohort V: ~ 6 mg/kg Raltegravir OGS BID

Reporting group description:

Participants ≥ 4 weeks to <6 months of age who received a weight based dose of ~6 mg/kg raltegravir OGS BID. Dose selection confirmed the ~6mg/kg dose thus all participants continued at this dose.

Serious adverse events	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 71 (28.17%)	1 / 16 (6.25%)	6 / 18 (33.33%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypovolaemic shock			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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			
Lipoma excision			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (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
Social circumstances			
Treatment noncompliance			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Reproductive system and breast disorders			
Vaginal haemorrhage			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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			
Asthma			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Dyspnoea			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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 distress			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Bipolar disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Depression			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Suicidal behaviour			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (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
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase abnormal			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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			
Post procedural complication			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Seizure			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Neutropenia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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 pain			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (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
Colitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Oesophagitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Hepatobiliary disorders			
Drug-induced liver injury			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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			
Dyshidrotic eczema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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 erythematous			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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			
Acute kidney injury			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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 and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute sinusitis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (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
Appendicitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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 respiratory tract infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterium avium complex infection			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Periorbital cellulitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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	6 / 71 (8.45%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Pneumonia viral			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection viral			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Septic shock			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Varicella			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella zoster virus infection			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Metabolism and nutrition disorders			
Cachexia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Failure to thrive			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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
Hyperglycaemia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (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	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
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	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 21 (19.05%)	6 / 14 (42.86%)	4 / 12 (33.33%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Hypovolaemic shock			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
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			
Lipoma excision			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Pyrexia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			
Treatment noncompliance			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			

Vaginal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Asthma			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (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 / 21 (0.00%)	2 / 14 (14.29%)	0 / 12 (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
Pneumothorax			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 distress			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Agitation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Suicidal behaviour			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 bilirubin increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (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
Lipase abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (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
Neutrophil count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Post procedural complication			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Febrile convulsion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurological symptom			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Anaemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (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
Neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Drug-induced liver injury			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (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 and subcutaneous tissue disorders			
Dyshidrotic eczema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (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
Rash erythematous			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Pain in extremity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Abdominal abscess			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (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
Acute sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
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	2 / 21 (9.52%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (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
Pneumonia viral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 viral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varicella			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (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
Varicella zoster virus infection			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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			
Cachexia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
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 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (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
Hypokalaemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Cohort I: 200 to 600 mg Raltegravir PFC tablets BID	Cohort IIA: 200 to 400 mg Raltegravir PFC tablets BID	Cohort IIB: ~ 6 to 8 mg/kg Raltegravir CH tablets BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	69 / 71 (97.18%)	16 / 16 (100.00%)	18 / 18 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			

subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Lipoma			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Skin papilloma			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	4	0	2
Uterine leiomyoma			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pallor			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pregnancy, puerperium and perinatal conditions			
First trimester pregnancy			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pregnancy			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Chest pain			

subjects affected / exposed	7 / 71 (9.86%)	2 / 16 (12.50%)	3 / 18 (16.67%)
occurrences (all)	7	2	3
Chills			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Crepitations			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Crying			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cyst			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	7 / 71 (9.86%)	1 / 16 (6.25%)	2 / 18 (11.11%)
occurrences (all)	7	1	2
Influenza like illness			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	5	0	1
Injection site mass			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Injection site oedema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Local swelling			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Localised oedema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	6 / 71 (8.45%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	6	0	1
Mass			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Nodule			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Pain			
subjects affected / exposed	4 / 71 (5.63%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	4	1	1
Peripheral swelling			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	2 / 18 (11.11%)
occurrences (all)	2	1	2
Puncture site discharge			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	33 / 71 (46.48%)	10 / 16 (62.50%)	12 / 18 (66.67%)
occurrences (all)	33	10	12
Secretion discharge			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Tenderness			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Immune reconstitution inflammatory syndrome			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
Victim of sexual abuse			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast discharge			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Breast pain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Breast tenderness			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cervical dysplasia			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Gynaecomastia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Haemorrhagic ovarian cyst			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Male sexual dysfunction			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Metrorrhagia			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Perineal erythema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Polycystic ovaries			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Testicular pain			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Testicular swelling			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Uterine haemorrhage			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vaginal discharge			
subjects affected / exposed	7 / 71 (9.86%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	7	1	0
Vaginal haemorrhage			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vaginal odour			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vaginal ulceration			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal discomfort			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal pruritus			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Vulvovaginal rash			

subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	3 / 71 (4.23%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	3	1	0
Asthma exercise induced			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Atelectasis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Bronchial hyperreactivity			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Cough			
subjects affected / exposed	48 / 71 (67.61%)	11 / 16 (68.75%)	11 / 18 (61.11%)
occurrences (all)	48	11	11
Dysphonia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	10 / 71 (14.08%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	10	0	2
Dyspnoea exertional			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
Haemoptysis			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hypoxia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Idiopathic interstitial pneumonia			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	32 / 71 (45.07%)	6 / 16 (37.50%)	12 / 18 (66.67%)
occurrences (all)	32	6	12
Nasal discharge discolouration			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Nasal obstruction			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Nasal oedema			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Nasal pruritus			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Nasal turbinate abnormality			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal discomfort			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	28 / 71 (39.44%)	6 / 16 (37.50%)	8 / 18 (44.44%)
occurrences (all)	28	6	8
Oropharyngeal plaque			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Paranasal sinus discomfort			

subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pharyngeal erythema			
subjects affected / exposed	4 / 71 (5.63%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	4	1	1
Pharyngeal exudate			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Pharyngeal inflammation			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pharyngeal ulceration			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1
Pulmonary congestion			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Pulmonary oedema			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Rales			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Respiratory distress			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Respiratory tract congestion			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	5	0	1
Rhinorrhoea			

subjects affected / exposed	26 / 71 (36.62%)	2 / 16 (12.50%)	9 / 18 (50.00%)
occurrences (all)	26	2	9
Rhonchi			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Sinus pain			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sneezing			
subjects affected / exposed	3 / 71 (4.23%)	3 / 16 (18.75%)	1 / 18 (5.56%)
occurrences (all)	3	3	1
Snoring			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sputum discoloured			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Tachypnoea			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Tonsillar inflammation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Wheezing			

subjects affected / exposed	12 / 71 (16.90%)	4 / 16 (25.00%)	3 / 18 (16.67%)
occurrences (all)	12	4	3
Psychiatric disorders			
Abnormal behaviour			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
Adjustment disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Agitation			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Anger			
subjects affected / exposed	3 / 71 (4.23%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	3	1	0
Anxiety			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Attention deficit/hyperactivity disorder			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Autism spectrum disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Conduct disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	8 / 71 (11.27%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	8	0	1
Generalised anxiety disorder			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hallucination, auditory			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Learning disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Major depression			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Mental status changes			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Mood swings			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Nightmare			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Oppositional defiant disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Post-traumatic stress disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Psychotic disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Reading disorder			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Restlessness			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Sexually inappropriate behaviour			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sleep terror			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	20 / 71 (28.17%)	2 / 16 (12.50%)	6 / 18 (33.33%)
occurrences (all)	20	2	6
Aspartate aminotransferase increased			
subjects affected / exposed	15 / 71 (21.13%)	3 / 16 (18.75%)	4 / 18 (22.22%)
occurrences (all)	15	3	4
Blood albumin decreased			
subjects affected / exposed	7 / 71 (9.86%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	7	2	0
Blood alkaline phosphatase increased			
subjects affected / exposed	10 / 71 (14.08%)	3 / 16 (18.75%)	1 / 18 (5.56%)
occurrences (all)	10	3	1
Blood bicarbonate decreased			
subjects affected / exposed	21 / 71 (29.58%)	1 / 16 (6.25%)	5 / 18 (27.78%)
occurrences (all)	21	1	5
Blood bilirubin increased			
subjects affected / exposed	14 / 71 (19.72%)	5 / 16 (31.25%)	7 / 18 (38.89%)
occurrences (all)	14	5	7
Blood calcium decreased			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
Blood calcium increased			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood cholesterol increased			

subjects affected / exposed	12 / 71 (16.90%)	4 / 16 (25.00%)	6 / 18 (33.33%)
occurrences (all)	12	4	6
Blood creatinine increased			
subjects affected / exposed	9 / 71 (12.68%)	3 / 16 (18.75%)	1 / 18 (5.56%)
occurrences (all)	9	3	1
Blood glucose decreased			
subjects affected / exposed	26 / 71 (36.62%)	6 / 16 (37.50%)	9 / 18 (50.00%)
occurrences (all)	26	6	9
Blood glucose increased			
subjects affected / exposed	15 / 71 (21.13%)	5 / 16 (31.25%)	0 / 18 (0.00%)
occurrences (all)	15	5	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood lactic acid increased			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Blood magnesium decreased			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Blood pH increased			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Blood phosphorus decreased			
subjects affected / exposed	19 / 71 (26.76%)	2 / 16 (12.50%)	4 / 18 (22.22%)
occurrences (all)	19	2	4
Blood potassium decreased			
subjects affected / exposed	15 / 71 (21.13%)	5 / 16 (31.25%)	1 / 18 (5.56%)
occurrences (all)	15	5	1
Blood potassium increased			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood pressure decreased			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Blood pressure diastolic increased			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood pressure increased			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood sodium decreased			
subjects affected / exposed	27 / 71 (38.03%)	5 / 16 (31.25%)	6 / 18 (33.33%)
occurrences (all)	27	5	6
Blood sodium increased			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Blood triglycerides increased			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Blood uric acid increased			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Blood urine present			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Breath sounds abnormal			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	3 / 18 (16.67%)
occurrences (all)	3	0	3
Chlamydia test positive			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram abnormal			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			
subjects affected / exposed	7 / 71 (9.86%)	3 / 16 (18.75%)	1 / 18 (5.56%)
occurrences (all)	7	3	1

Helicobacter test positive			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	8 / 71 (11.27%)	3 / 16 (18.75%)	1 / 18 (5.56%)
occurrences (all)	8	3	1
Low density lipoprotein increased			
subjects affected / exposed	10 / 71 (14.08%)	1 / 16 (6.25%)	4 / 18 (22.22%)
occurrences (all)	10	1	4
Neutrophil count decreased			
subjects affected / exposed	25 / 71 (35.21%)	7 / 16 (43.75%)	5 / 18 (27.78%)
occurrences (all)	25	7	5
Platelet count decreased			
subjects affected / exposed	5 / 71 (7.04%)	1 / 16 (6.25%)	3 / 18 (16.67%)
occurrences (all)	5	1	3
Weight decreased			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
White blood cell count decreased			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Contusion			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Genital injury			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	5	0	2
Laceration			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ligament rupture			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lip injury			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Meniscus injury			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Post procedural swelling			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Post-traumatic pain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Stoma site rash			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Wrist fracture			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Cerebral palsy			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Congestive cardiomyopathy			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Left ventricular hypertrophy			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	5	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	9 / 71 (12.68%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	9	1	0
Dysarthria			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Dyscalculia			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dysgraphia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dyslalia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Dyslexia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Epilepsy			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Facial paralysis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Facial paresis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Febrile convulsion			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	29 / 71 (40.85%)	10 / 16 (62.50%)	4 / 18 (22.22%)
occurrences (all)	29	10	4
Hyperreflexia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypertonia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Language disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Meningeal disorder			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Monoparesis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Muscle spasticity			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Paraesthesia			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Psychomotor hyperactivity			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Seizure			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Speech disorder			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Syncope			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Thrombotic stroke			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Unresponsive to stimuli			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Haemolytic anaemia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	3 / 71 (4.23%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Lymph node pain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lymphadenitis			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Lymphadenopathy			
subjects affected / exposed	12 / 71 (16.90%)	5 / 16 (31.25%)	2 / 18 (11.11%)
occurrences (all)	12	5	2
Neutropenia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Splenomegaly			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Conductive deafness			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Deafness			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ear canal erythema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Ear discomfort			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	17 / 71 (23.94%)	0 / 16 (0.00%)	6 / 18 (33.33%)
occurrences (all)	17	0	6
Ear pruritus			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Eustachian tube dysfunction			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Excessive cerumen production			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Hypoacusis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Middle ear effusion			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Noninfective myringitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	4	0	2
Tinnitus			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tympanic membrane hyperaemia			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Tympanosclerosis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Conjunctival pallor			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Eye discharge			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Eye irritation			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Eye pain			

subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	5	0	1
Eye pruritus			
subjects affected / exposed	3 / 71 (4.23%)	2 / 16 (12.50%)	1 / 18 (5.56%)
occurrences (all)	3	2	1
Eye swelling			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Eyelid oedema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Eyelid thickening			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Iris disorder			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Keratitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	8 / 71 (11.27%)	1 / 16 (6.25%)	3 / 18 (16.67%)
occurrences (all)	8	1	3
Periorbital oedema			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Photophobia			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Vision blurred			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Visual impairment			

subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Abdominal hernia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	20 / 71 (28.17%)	5 / 16 (31.25%)	3 / 18 (16.67%)
occurrences (all)	20	5	3
Abdominal pain lower			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Abdominal pain upper			
subjects affected / exposed	9 / 71 (12.68%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	9	1	1
Abdominal tenderness			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Anal pruritus			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Anorectal discomfort			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Breath odour			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2

Cheilitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	5	0	1
Dental caries			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	22 / 71 (30.99%)	2 / 16 (12.50%)	6 / 18 (33.33%)
occurrences (all)	22	2	6
Dyspepsia			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Flatulence			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Food poisoning			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Gingival erythema			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Gingival pain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Infantile spitting up			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Infantile vomiting			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Inflammatory bowel disease			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lip discolouration			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lip ulceration			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Mouth ulceration			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	3	0	1
Nausea			
subjects affected / exposed	23 / 71 (32.39%)	5 / 16 (31.25%)	5 / 18 (27.78%)
occurrences (all)	23	5	5
Noninfective gingivitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oral discharge			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oral disorder			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0

Oral mucosal blistering			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oral mucosal erythema			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Parotid gland enlargement			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Stomatitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	6 / 71 (8.45%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	6	1	0
Vomiting			
subjects affected / exposed	26 / 71 (36.62%)	6 / 16 (37.50%)	8 / 18 (44.44%)
occurrences (all)	26	6	8
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hepatomegaly			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Ocular icterus			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			

Acanthosis nigricans			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Acne			
subjects affected / exposed	9 / 71 (12.68%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	9	1	0
Alopecia			
subjects affected / exposed	1 / 71 (1.41%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Blister			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Dermatitis allergic			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	4	0	2
Dermatitis atopic			
subjects affected / exposed	4 / 71 (5.63%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	4	1	0
Dermatitis diaper			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Dry skin			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	2	1	1
Dyshidrotic eczema			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	3	0	2
Erythema			
subjects affected / exposed	9 / 71 (12.68%)	2 / 16 (12.50%)	2 / 18 (11.11%)
occurrences (all)	9	2	2

Hyperhidrosis			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Macule			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Nail discolouration			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Night sweats			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pain of skin			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Papule			
subjects affected / exposed	7 / 71 (9.86%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	7	2	0
Petechiae			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Photosensitivity reaction			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pityriasis alba			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	12 / 71 (16.90%)	3 / 16 (18.75%)	2 / 18 (11.11%)
occurrences (all)	12	3	2
Pruritus generalised			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1

Rash			
subjects affected / exposed	8 / 71 (11.27%)	6 / 16 (37.50%)	2 / 18 (11.11%)
occurrences (all)	8	6	2
Rash generalised			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	3 / 18 (16.67%)
occurrences (all)	4	0	3
Rash macular			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	2	1	1
Rash maculo-papular			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Rash papular			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Scab			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Skin discolouration			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Skin exfoliation			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Skin hyperpigmentation			
subjects affected / exposed	1 / 71 (1.41%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	1	2	0
Skin hypopigmentation			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Skin lesion			
subjects affected / exposed	7 / 71 (9.86%)	3 / 16 (18.75%)	0 / 18 (0.00%)
occurrences (all)	7	3	0

Skin plaque			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin ulcer			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	5 / 71 (7.04%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	5	1	1
Trichorrhexis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	3 / 71 (4.23%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Haematuria			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Kidney enlargement			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Proteinuria			

subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Tubulointerstitial nephritis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Urine odour abnormal			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	10 / 71 (14.08%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	10	0	0
Back pain			
subjects affected / exposed	16 / 71 (22.54%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	16	1	0
Costochondritis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Facial asymmetry			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Flank pain			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Groin pain			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Head deformity			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Joint effusion			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Joint stiffness			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Joint swelling			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Kyphosis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Limb discomfort			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	4	0	1
Muscle twitching			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal discomfort			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Myalgia			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Pain in extremity			
subjects affected / exposed	10 / 71 (14.08%)	3 / 16 (18.75%)	3 / 18 (16.67%)
occurrences (all)	10	3	3
Pain in jaw			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pathological fracture			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Spinal pain			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Acarodermatitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Acute sinusitis			
subjects affected / exposed	5 / 71 (7.04%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	5	1	1
Bacterial sepsis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Bacterial vaginosis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Body tinea			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Breast abscess			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Bronchiolitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	4 / 71 (5.63%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	4	2	0

Bronchitis viral			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Candida infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Cervicitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cervicitis human papilloma virus			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cervicitis trichomonal			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Chlamydial cervicitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Chronic sinusitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile colitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	4 / 71 (5.63%)	3 / 16 (18.75%)	3 / 18 (16.67%)
occurrences (all)	4	3	3
Conjunctivitis bacterial			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Coxsackie viral infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Dermatophytosis of nail			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dysentery			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Epididymitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Escherichia urinary tract infection			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Fungal skin infection			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Gastroenteritis			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	4 / 18 (22.22%)
occurrences (all)	5	0	4
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
H1N1 influenza			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
HIV associated nephropathy			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
HIV wasting syndrome			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Herpes simplex			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	5 / 71 (7.04%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	5	1	0
Hymenolepiasis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	0 / 71 (0.00%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Infection parasitic			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	2 / 71 (2.82%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	2	2	0
Laryngitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Latent tuberculosis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lice infestation			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Meningitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Molluscum contagiosum			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	1	0	2
Mycobacterium avium complex infection			

subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Mycoplasma infection			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oesophageal candidiasis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Oral candidiasis			
subjects affected / exposed	7 / 71 (9.86%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	7	0	0
Oral hairy leukoplakia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	2 / 18 (11.11%)
occurrences (all)	1	1	2
Orchitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal gonococcal infection			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	5 / 71 (7.04%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	5	0	1
Otitis media			
subjects affected / exposed	10 / 71 (14.08%)	2 / 16 (12.50%)	4 / 18 (22.22%)
occurrences (all)	10	2	4
Otitis media acute			

subjects affected / exposed	4 / 71 (5.63%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	4	1	1
Otitis media chronic			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Pancreatitis viral			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Persistent generalised lymphadenopathy			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Pharyngeal chlamydia infection			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	3 / 18 (16.67%)
occurrences (all)	4	0	3
Pharyngitis streptococcal			
subjects affected / exposed	3 / 71 (4.23%)	2 / 16 (12.50%)	0 / 18 (0.00%)
occurrences (all)	3	2	0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	3 / 71 (4.23%)	1 / 16 (6.25%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Pneumonia bacterial			
subjects affected / exposed	4 / 71 (5.63%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	4	1	0
Proctitis chlamydial			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Proctitis gonococcal			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Purulent discharge			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Rash pustular			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Rubella			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Sinusitis bacterial			
subjects affected / exposed	2 / 71 (2.82%)	3 / 16 (18.75%)	3 / 18 (16.67%)
occurrences (all)	2	3	3
Skin candida			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Staphylococcal abscess			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Subcutaneous abscess			
subjects affected / exposed	0 / 71 (0.00%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Tinea capitis			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Tinea faciei			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Tinea infection			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Tinea pedis			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Tinea versicolour			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 71 (1.41%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Urethritis chlamydial			
subjects affected / exposed	4 / 71 (5.63%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	4	0	0
Urethritis gonococcal			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection bacterial			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Urinary tract infection staphylococcal			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Vaginitis chlamydial			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Varicella			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
subjects affected / exposed	2 / 71 (2.82%)	1 / 16 (6.25%)	0 / 18 (0.00%)
occurrences (all)	2	1	0
Vulvovaginitis gonococcal			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Body fat disorder			
subjects affected / exposed	3 / 71 (4.23%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Decreased appetite			
subjects affected / exposed	9 / 71 (12.68%)	1 / 16 (6.25%)	3 / 18 (16.67%)
occurrences (all)	9	1	3
Dehydration			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Failure to thrive			

subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperlactacidaemia			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	2 / 71 (2.82%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Lactic acidosis			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Malnutrition			
subjects affected / exposed	0 / 71 (0.00%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	0	0	0
Metabolic syndrome			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Obesity			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 71 (1.41%)	0 / 16 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Cohort III: ~ 6 mg/kg Raltegravir CH tablets BID	Cohort IV: ~ 6 mg/kg Raltegravir OGS BID	Cohort V: ~ 6 mg/kg Raltegravir OGS BID
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 21 (100.00%)	14 / 14 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lipoma			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Uterine leiomyoma			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pallor			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
First trimester pregnancy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pregnancy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Crepitations			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Crying			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cyst			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 21 (9.52%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Influenza like illness			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injection site mass			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Local swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Mass			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nodule			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Puncture site discharge			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	10 / 21 (47.62%)	8 / 14 (57.14%)	6 / 12 (50.00%)
occurrences (all)	10	8	6
Secretion discharge			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenderness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune reconstitution inflammatory syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Social circumstances			

Victim of sexual abuse			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Breast discharge			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breast tenderness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cervical dysplasia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysfunctional uterine bleeding			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gynaecomastia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemorrhagic ovarian cyst			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Male sexual dysfunction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metrorrhagia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Perineal erythema			

subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Polycystic ovaries			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Testicular pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Testicular swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Uterine haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal odour			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaginal ulceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pruritus			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal rash			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal			

disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	2 / 21 (9.52%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Asthma exercise induced			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Atelectasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchial hyperreactivity			
subjects affected / exposed	2 / 21 (9.52%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Cough			
subjects affected / exposed	16 / 21 (76.19%)	9 / 14 (64.29%)	10 / 12 (83.33%)
occurrences (all)	16	9	10
Dysphonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 21 (4.76%)	3 / 14 (21.43%)	2 / 12 (16.67%)
occurrences (all)	1	3	2
Dyspnoea exertional			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Idiopathic interstitial pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	8 / 21 (38.10%)	6 / 14 (42.86%)	9 / 12 (75.00%)
occurrences (all)	8	6	9
Nasal discharge discolouration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal pruritus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasal turbinate abnormality			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal plaque			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngeal erythema			

subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Pharyngeal exudate			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngeal inflammation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngeal ulceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary congestion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rales			
subjects affected / exposed	1 / 21 (4.76%)	2 / 14 (14.29%)	1 / 12 (8.33%)
occurrences (all)	1	2	1
Respiratory distress			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Respiratory tract congestion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	13 / 21 (61.90%)	6 / 14 (42.86%)	10 / 12 (83.33%)
occurrences (all)	13	6	10
Rhonchi			

subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Sinus congestion			
subjects affected / exposed	2 / 21 (9.52%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Sinus pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sleep apnoea syndrome			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sneezing			
subjects affected / exposed	2 / 21 (9.52%)	2 / 14 (14.29%)	1 / 12 (8.33%)
occurrences (all)	2	2	1
Snoring			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sputum discoloured			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachypnoea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillar hypertrophy			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Tonsillar inflammation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	4 / 21 (19.05%)	3 / 14 (21.43%)	0 / 12 (0.00%)
occurrences (all)	4	3	0
Psychiatric disorders			

Abnormal behaviour			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Adjustment disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Agitation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anger			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Attention deficit/hyperactivity disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Autism spectrum disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conduct disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Generalised anxiety disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Learning disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Major depression			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mental status changes			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mood swings			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nightmare			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oppositional defiant disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Post-traumatic stress disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychotic disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Reading disorder			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sexually inappropriate behaviour			

subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sleep terror			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	4 / 21 (19.05%)	1 / 14 (7.14%)	3 / 12 (25.00%)
occurrences (all)	4	1	3
Aspartate aminotransferase increased			
subjects affected / exposed	5 / 21 (23.81%)	4 / 14 (28.57%)	3 / 12 (25.00%)
occurrences (all)	5	4	3
Blood albumin decreased			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 21 (19.05%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	4	0	1
Blood bicarbonate decreased			
subjects affected / exposed	6 / 21 (28.57%)	4 / 14 (28.57%)	4 / 12 (33.33%)
occurrences (all)	6	4	4
Blood bilirubin increased			
subjects affected / exposed	1 / 21 (4.76%)	2 / 14 (14.29%)	1 / 12 (8.33%)
occurrences (all)	1	2	1
Blood calcium decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood calcium increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood cholesterol increased			
subjects affected / exposed	8 / 21 (38.10%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	8	1	0
Blood creatinine increased			

subjects affected / exposed	2 / 21 (9.52%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
Blood glucose decreased			
subjects affected / exposed	7 / 21 (33.33%)	5 / 14 (35.71%)	1 / 12 (8.33%)
occurrences (all)	7	5	1
Blood glucose increased			
subjects affected / exposed	2 / 21 (9.52%)	9 / 14 (64.29%)	3 / 12 (25.00%)
occurrences (all)	2	9	3
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood lactic acid increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood magnesium decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pH increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus decreased			
subjects affected / exposed	1 / 21 (4.76%)	3 / 14 (21.43%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Blood potassium decreased			
subjects affected / exposed	2 / 21 (9.52%)	4 / 14 (28.57%)	1 / 12 (8.33%)
occurrences (all)	2	4	1
Blood potassium increased			
subjects affected / exposed	4 / 21 (19.05%)	4 / 14 (28.57%)	8 / 12 (66.67%)
occurrences (all)	4	4	8
Blood pressure decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood pressure diastolic increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2

Blood pressure increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood pressure systolic increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood sodium decreased			
subjects affected / exposed	7 / 21 (33.33%)	4 / 14 (28.57%)	5 / 12 (41.67%)
occurrences (all)	7	4	5
Blood sodium increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Blood urine present			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breath sounds abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chlamydia test positive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram abnormal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	1 / 21 (4.76%)	3 / 14 (21.43%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Helicobacter test positive			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Lipase increased			
subjects affected / exposed	1 / 21 (4.76%)	3 / 14 (21.43%)	2 / 12 (16.67%)
occurrences (all)	1	3	2
Low density lipoprotein increased			
subjects affected / exposed	8 / 21 (38.10%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	8	0	0
Neutrophil count decreased			
subjects affected / exposed	11 / 21 (52.38%)	10 / 14 (71.43%)	2 / 12 (16.67%)
occurrences (all)	11	10	2
Platelet count decreased			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Weight decreased			
subjects affected / exposed	1 / 21 (4.76%)	3 / 14 (21.43%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
White blood cell count decreased			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Clavicle fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 21 (0.00%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Genital injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hand fracture			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip injury			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Meniscus injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Post procedural swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Post-traumatic pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stoma site rash			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic			

disorders			
Cerebral palsy			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Atrioventricular block first degree			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congestive cardiomyopathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Left ventricular hypertrophy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysarthria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dyscalculia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dysgraphia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dyslalia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Dyslexia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Epilepsy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial paralysis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial paresis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Febrile convulsion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Hyperreflexia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypersomnia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypertonia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Language disorder			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Meningeal disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Monoparesis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasticity			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Posterior reversible encephalopathy syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Speech disorder			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Thrombotic stroke			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Unresponsive to stimuli			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Haemolytic anaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Immune thrombocytopenic purpura			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	1 / 21 (4.76%)	3 / 14 (21.43%)	1 / 12 (8.33%)
occurrences (all)	1	3	1
Lymph node pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Lymphadenopathy			
subjects affected / exposed	7 / 21 (33.33%)	4 / 14 (28.57%)	5 / 12 (41.67%)
occurrences (all)	7	4	5
Neutropenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pancytopenia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Splenomegaly			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Thrombocytopenia			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Conductive deafness			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Deafness			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ear canal erythema			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Ear congestion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Ear discomfort			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	4 / 21 (19.05%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	4	2	0
Ear pruritus			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Eustachian tube dysfunction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Excessive cerumen production			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Hypoacusis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Middle ear effusion			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Noninfective myringitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Otorrhoea			
subjects affected / exposed	3 / 21 (14.29%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	3	0	1
Tinnitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane hyperaemia			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tympanosclerosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctival hyperaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctival pallor			
subjects affected / exposed	0 / 21 (0.00%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Eye discharge			
subjects affected / exposed	3 / 21 (14.29%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Eye irritation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			

subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	2 / 12 (16.67%)
occurrences (all)	2	1	2
Eye swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Eyelid thickening			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iris disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Keratitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Periorbital oedema			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Photophobia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Abdominal hernia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 21 (9.52%)	3 / 14 (21.43%)	0 / 12 (0.00%)
occurrences (all)	2	3	0
Abdominal pain lower			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Abdominal tenderness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anal pruritus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Anorectal discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Aphthous ulcer			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Breath odour			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Dental caries			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	8 / 21 (38.10%)	9 / 14 (64.29%)	7 / 12 (58.33%)
occurrences (all)	8	9	7
Dyspepsia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Food poisoning			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival erythema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Infantile spitting up			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Infantile vomiting			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Inflammatory bowel disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip discolouration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lip ulceration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Noninfective gingivitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral discharge			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral disorder			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	2 / 12 (16.67%)
occurrences (all)	2	1	2
Oral mucosal blistering			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Oral mucosal erythema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Parotid gland enlargement			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 21 (0.00%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Toothache			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	9 / 21 (42.86%)	6 / 14 (42.86%)	3 / 12 (25.00%)
occurrences (all)	9	6	3
Hepatobiliary disorders			
Hepatic steatosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hepatomegaly			
subjects affected / exposed	3 / 21 (14.29%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	3	2	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Ocular icterus			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Skin and subcutaneous tissue disorders			
Acanthosis nigricans			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Acne			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 21 (0.00%)	3 / 14 (21.43%)	1 / 12 (8.33%)
occurrences (all)	0	3	1
Dermatitis atopic			
subjects affected / exposed	0 / 21 (0.00%)	2 / 14 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
Dermatitis diaper			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Drug eruption			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Dyshidrotic eczema			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 21 (4.76%)	2 / 14 (14.29%)	1 / 12 (8.33%)
occurrences (all)	1	2	1
Erythema			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Macule			

subjects affected / exposed	4 / 21 (19.05%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	4	0	0
Nail discolouration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pain of skin			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Papule			
subjects affected / exposed	3 / 21 (14.29%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Petechiae			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pityriasis alba			
subjects affected / exposed	2 / 21 (9.52%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Pityriasis rosea			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Pruritus generalised			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	6 / 21 (28.57%)	7 / 14 (50.00%)	9 / 12 (75.00%)
occurrences (all)	6	7	9
Rash generalised			

subjects affected / exposed	0 / 21 (0.00%)	2 / 14 (14.29%)	3 / 12 (25.00%)
occurrences (all)	0	2	3
Rash macular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Scab			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	1	0	1
Skin discolouration			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin hyperpigmentation			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Skin hypopigmentation			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	3 / 21 (14.29%)	1 / 14 (7.14%)	2 / 12 (16.67%)
occurrences (all)	3	1	2
Skin plaque			
subjects affected / exposed	3 / 21 (14.29%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Skin ulcer			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Trichorrhexis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	2 / 21 (9.52%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Kidney enlargement			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Urine odour abnormal			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Costochondritis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Facial asymmetry			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Head deformity			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Joint effusion			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Kyphosis			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Muscle twitching			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pathological fracture			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Acarodermatitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Acute sinusitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Bacterial sepsis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	1 / 21 (4.76%)	2 / 14 (14.29%)	3 / 12 (25.00%)
occurrences (all)	1	2	3
Breast abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Bronchitis			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Bronchitis viral			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Cellulitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cervicitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cervicitis human papilloma virus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cervicitis trichomonal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chlamydial cervicitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	4 / 21 (19.05%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	4	1	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Coxsackie viral infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dermatophytosis of nail			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dysentery			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Epididymitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Fungal skin infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	6 / 21 (28.57%)	7 / 14 (50.00%)	3 / 12 (25.00%)
occurrences (all)	6	7	3
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
H1N1 influenza			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HIV associated nephropathy			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HIV wasting syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Herpes simplex			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Hymenolepiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	9 / 21 (42.86%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	9	1	1
Infection parasitic			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Latent tuberculosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Lice infestation			
subjects affected / exposed	2 / 21 (9.52%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Meningitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Molluscum contagiosum			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Mycobacterium avium complex infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mycoplasma infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oesophageal candidiasis			

subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Onychomycosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	2 / 21 (9.52%)	2 / 14 (14.29%)	1 / 12 (8.33%)
occurrences (all)	2	2	1
Oral hairy leukoplakia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	3 / 21 (14.29%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Orchitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal gonococcal infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	9 / 21 (42.86%)	4 / 14 (28.57%)	2 / 12 (16.67%)
occurrences (all)	9	4	2
Otitis media acute			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	1	1	0
Otitis media chronic			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pancreatitis viral			

subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Parotitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Persistent generalised lymphadenopathy			
subjects affected / exposed	1 / 21 (4.76%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Pharyngeal chlamydia infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 21 (9.52%)	6 / 14 (42.86%)	4 / 12 (33.33%)
occurrences (all)	2	6	4
Pharyngitis streptococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 21 (0.00%)	2 / 14 (14.29%)	1 / 12 (8.33%)
occurrences (all)	0	2	1
Pneumonia bacterial			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Proctitis chlamydial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Proctitis gonococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

Purulent discharge			
subjects affected / exposed	2 / 21 (9.52%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Rash pustular			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Rubella			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Sialoadenitis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Sinusitis bacterial			
subjects affected / exposed	5 / 21 (23.81%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	5	2	0
Skin candida			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	2	1	1
Skin infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Staphylococcal abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea capitis			
subjects affected / exposed	4 / 21 (19.05%)	2 / 14 (14.29%)	2 / 12 (16.67%)
occurrences (all)	4	2	2

Tinea faciei			
subjects affected / exposed	1 / 21 (4.76%)	2 / 14 (14.29%)	0 / 12 (0.00%)
occurrences (all)	1	2	0
Tinea infection			
subjects affected / exposed	2 / 21 (9.52%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Tinea pedis			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	3 / 21 (14.29%)	3 / 14 (21.43%)	1 / 12 (8.33%)
occurrences (all)	3	3	1
Tooth abscess			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urethritis chlamydial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urethritis gonococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urinary tract infection staphylococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Vaginitis chlamydial			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vulvovaginitis			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Vulvovaginitis gonococcal			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Body fat disorder			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 21 (14.29%)	4 / 14 (28.57%)	3 / 12 (25.00%)
occurrences (all)	3	4	3
Dehydration			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Failure to thrive			
subjects affected / exposed	1 / 21 (4.76%)	3 / 14 (21.43%)	3 / 12 (25.00%)
occurrences (all)	1	3	3
Hyperlactacidaemia			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hyperlipidaemia			

subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lactic acidosis			
subjects affected / exposed	1 / 21 (4.76%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Malnutrition			
subjects affected / exposed	0 / 21 (0.00%)	1 / 14 (7.14%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Metabolic syndrome			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 21 (0.00%)	0 / 14 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 June 2008	Amendment 1: Added references to a third potential formulation (in development), to be studied in Cohort IV (≥6 months to <2 years) and Cohort V (≥4 weeks to <6 months); added information on 5 year follow-up of participants both on-drug and off-drug including schedules of evaluations; updated inclusion and exclusion criteria.
09 April 2010	Amendment 2: Increased total study sample size to 160 participants; specified that the raltegravir formulation to be evaluated in participants ≥4 weeks to <2 years of age was the oral granules for suspension, and added specific dosing instruction, updated inclusion and exclusion criteria, and added a dried blood spot assay.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported