



Clinical trial results:

A Phase IIb study to select a once daily oral dose of GSK1349572 administered with either abacavir/lamivudine or tenofovir/emtricitabine in HIV-1 infected antiretroviral therapy naïve adult subjects.

Summary

EudraCT number	2009-010269-21
Trial protocol	DE ES FR IT
Global end of trial date	22 December 2016

Results information

Result version number	v1 (current)
This version publication date	30 December 2017
First version publication date	30 December 2017

Trial information

Trial identification

Sponsor protocol code	112276
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,
Scientific contact	GSK Response Center, GlaxoSmithKline, 1 866-435-7343,

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 July 2017
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	22 December 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To select a GSK1349572 once daily dose for further evaluation in Phase III based on a comparison of the Week 16 antiviral activity and tolerability of a range of oral doses of GSK1349572 in Human Immunodeficiency Virus Type 1 (HIV-1) infected therapy-naïve adult participants.

Protection of trial subjects:

99999

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 July 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	86 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 81
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Germany: 28
Country: Number of subjects enrolled	Italy: 28
Country: Number of subjects enrolled	Russian Federation: 19
Country: Number of subjects enrolled	Spain: 31
Worldwide total number of subjects	205
EEA total number of subjects	105

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	203
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Randomization Phase participants received Dolutegravir (DTG 10, 25 or 50 milligrams[mg]) with Placebo/Efavirenz (EFV) for 96 Weeks . DTG participants who completed 96 Weeks continued or were switched to receive DTG 50 mg in Open label phase until DTG was locally available.

Pre-assignment

Screening details:

A total of 278 par were screened of which 70 were screen failures and 208 were randomized; 205 received at least one dose of study medication and comprised the Intent-To-Treat exposed (ITT-E) population. 17 participants out of 155 from DTG arm withdrew during Randomization phase and total 138 participants were enrolled in an Open-label phase.

Period 1

Period 1 title	Randomization Phase 96 Week
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	DTG 10 mg QD

Arm description:

Participants received DTG 10 mg, DTG matching placebo, and Abacavir/lamivudine (ABC/3TC) 600 mg/300 mg or tenofovir/emtricitabine (TDF/FTC) 300 mg/200 mg orally once daily (QD) for 96 weeks.

Arm type	Experimental
Investigational medicinal product name	Dolutegravir (DTG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received once daily 10 milligram (mg) oral tablet in Treatment Arm A, in Treatment Arm B once daily 25 mg oral tablet and Treatment Arm C two oral tablets of 25 mg GSK1349572 once daily

Investigational medicinal product name	Tenofovir disoproxil fumarate /Emtricitabine (TDF/FTC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a fixed dose combination tablet containing tenofovir disoproxil fumarate 300 mg and 200 mg of emtricitabine for once daily

Investigational medicinal product name	Abacavir/Lamivudine (ABC/3TC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a fixed dose combination tablet containing abacavir 600 mg and 300 mg of lamivudine for once daily

Arm title	DTG 25 mg QD
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Arm description:

Participants received DTG 25 mg, DTG matching placebo, and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.

Arm type	Experimental
Investigational medicinal product name	Dolutegravir (DTG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received once daily 10 milligram (mg) oral tablet in Treatment Arm A, in Treatment Arm B once daily 25 mg oral tablet and Treatment Arm C two oral tablets of 25 mg GSK1349572 once daily

Investigational medicinal product name	Abacavir/Lamivudine (ABC/3TC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a fixed dose combination tablet containing abacavir 600 mg and 300 mg of lamivudine for once daily

Investigational medicinal product name	Tenofovir disoproxil fumarate /Emtricitabine (TDF/FTC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a fixed dose combination tablet containing tenofovir disoproxil fumarate 300 mg and 200 mg of emtricitabine for once daily

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received matching placebo tablets once daily along with DTG

Arm title	DTG 50 mg QD
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Arm description:

Participants received DTG 50 mg matching placebo and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.

Arm type	Experimental
Investigational medicinal product name	Dolutegravir (DTG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received once daily 10 milligram (mg) oral tablet in Treatment Arm A, in Treatment Arm B once daily 25 mg oral tablet and Treatment Arm C two oral tablets of 25 mg GSK1349572 once daily

Investigational medicinal product name	Tenofovir disoproxil fumarate /Emtricitabine (TDF/FTC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet

Routes of administration	Oral use
Dosage and administration details:	
Participants received a fixed dose combination tablet containing tenofovir disoproxil fumarate 300 mg and 200 mg of emtricitabine for once daily	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received matching placebo tablets once daily along with DTG	
Investigational medicinal product name	Abacavir/Lamivudine (ABC/3TC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received a fixed dose combination tablet containing abacavir 600 mg and 300 mg of lamivudine for once daily	
Arm title	EFV 600 mg QD
Arm description:	
Participants received Efavirenz (EFV) 600 mg and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.	
Arm type	Active comparator
Investigational medicinal product name	Efavirenz (EFV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received 600 mg oral tablet of efavirenz once daily	
Investigational medicinal product name	Tenofovir disoproxil fumarate /Emtricitabine (TDF/FTC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received a fixed dose combination tablet containing tenofovir disoproxil fumarate 300 mg and 200 mg of emtricitabine for once daily	
Investigational medicinal product name	Abacavir/Lamivudine (ABC/3TC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details:	
Participants received a fixed dose combination tablet containing abacavir 600 mg and 300 mg of lamivudine for once daily	

Number of subjects in period 1	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD
Started	53	51	51
Completed	48	44	46
Not completed	5	7	5
Consent withdrawn by subject	2	1	1
Adverse event, non-fatal	1	1	2
Lost to follow-up	-	3	1
Lack of efficacy	1	1	-
Protocol deviation	1	1	1
Protocol-Defined Stopping Criteria	-	-	-

Number of subjects in period 1	EFV 600 mg QD
Started	50
Completed	40
Not completed	10
Consent withdrawn by subject	2
Adverse event, non-fatal	5
Lost to follow-up	2
Lack of efficacy	-
Protocol deviation	-
Protocol-Defined Stopping Criteria	1

Period 2

Period 2 title	Open-label phase
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Open-label DTG 50 mg QD
Arm description:	
All DTG participants were switched to or continued DTG 50 mg with either ABC/3TC orally at 600 mg/300 mg (1 tablet) or TDF/FTC orally QD during the Open label phase	
Arm type	Experimental
Investigational medicinal product name	Dolutegravir (DTG)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received once daily 10 milligram (mg) oral tablet in Treatment Arm A, in Treatment Arm B once daily 25 mg oral tablet and Treatment Arm C two oral tablets of 25 mg GSK1349572 once daily

Investigational medicinal product name	Tenofovir disoproxil fumarate /Emtricitabine (TDF/FTC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a fixed dose combination tablet containing tenofovir disoproxil fumarate 300 mg and 200 mg of emtricitabine for once daily

Investigational medicinal product name	Abacavir/Lamivudine (ABC/3TC) fixed dose combination
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants received a fixed dose combination tablet containing abacavir 600 mg and 300 mg of lamivudine for once daily

Number of subjects in period 2	Open-label DTG 50 mg QD
Started	138
Completed	88
Not completed	50
Consent withdrawn by subject	14
Physician decision	8
Adverse event, non-fatal	3
Lost to follow-up	12
Lack of efficacy	1
Protocol deviation	12

Baseline characteristics

Reporting groups

Reporting group title	DTG 10 mg QD
Reporting group description:	
Participants received DTG 10 mg, DTG matching placebo, and Abacavir/lamivudine (ABC/3TC) 600 mg/300 mg or tenofovir/emtricitabine (TDF/FTC) 300 mg/200 mg orally once daily (QD) for 96 weeks.	
Reporting group title	DTG 25 mg QD
Reporting group description:	
Participants received DTG 25 mg, DTG matching placebo, and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.	
Reporting group title	DTG 50 mg QD
Reporting group description:	
Participants received DTG 50 mg matching placebo and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.	
Reporting group title	EFV 600 mg QD
Reporting group description:	
Participants received Efavirenz (EFV) 600 mg and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.	

Reporting group values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD
Number of subjects	53	51	51
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
arithmetic mean	34.2	37.0	37.0
standard deviation	± 9.25	± 9.79	± 8.89
Gender categorical			
Units: Subjects			
Female	11	5	6
Male	42	46	45
Race/Ethnicity, Customized			
Units: Subjects			
African American/African Heritage (HER)	7	6	8
American Indian or Alaska Native	1	3	4
Japanese/East Asian HER/South East Asian HER	0	0	0
Native Hawaiian or other Pacific Islander	3	0	0
White	41	42	38
African American/African HER & White	0	0	1
Asian & White	1	0	0

Reporting group values	EFV 600 mg QD	Total	
Number of subjects	50	205	

Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	40.7 ± 11.19	-	
Gender categorical Units: Subjects			
Female	6	28	
Male	44	177	
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage (HER)	4	25	
American Indian or Alaska Native	2	10	
Japanese/East Asian HER/South East Asian HER	1	1	
Native Hawaiian or other Pacific Islander	0	3	
White	43	164	
African American/African HER & White	0	1	
Asian & White	0	1	

Subject analysis sets

Subject analysis set title	Overall DTG
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants who received DTG in any DTG treatment group (DTG 10 mg QD, DTG 25 mg QD, and DTG 50 mg QD)

Reporting group values	Overall DTG		
Number of subjects	142		
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	0 ± 0		
Gender categorical Units: Subjects			
Female	0		
Male	0		
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage (HER)	0		
American Indian or Alaska Native	0		

Japanese/East Asian HER/South East Asian HER	0		
Native Hawaiian or other Pacific Islander	0		
White	0		
African American/African HER & White	0		
Asian & White	0		

End points

End points reporting groups

Reporting group title	DTG 10 mg QD
Reporting group description: Participants received DTG 10 mg, DTG matching placebo, and Abacavir/lamivudine (ABC/3TC) 600 mg/300 mg or tenofovir/emtricitabine (TDF/FTC) 300 mg/200 mg orally once daily (QD) for 96 weeks.	
Reporting group title	DTG 25 mg QD
Reporting group description: Participants received DTG 25 mg, DTG matching placebo, and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.	
Reporting group title	DTG 50 mg QD
Reporting group description: Participants received DTG 50 mg matching placebo and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.	
Reporting group title	EFV 600 mg QD
Reporting group description: Participants received Efavirenz (EFV) 600 mg and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.	
Reporting group title	Open-label DTG 50 mg QD
Reporting group description: All DTG participants were switched to or continued DTG 50 mg with either ABC/3TC orally at 600 mg/300 mg (1 tablet) or TDF/FTC orally QD during the Open label phase	
Subject analysis set title	Overall DTG
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants who received DTG in any DTG treatment group (DTG 10 mg QD, DTG 25 mg QD, and DTG 50 mg QD)	

Primary: Number of participants with Human Immunodeficiency Virus Type 1 (HIV-1) ribonucleic acid (RNA) <50 copies/milliliter (c/mL) at Week 16

End point title	Number of participants with Human Immunodeficiency Virus Type 1 (HIV-1) ribonucleic acid (RNA) <50 copies/milliliter (c/mL) at Week 16 ^[1]
End point description: Plasma samples were collected for quantitative HIV-1 RNA analysis at Week 16. The analysis was performed using the time to loss of virological response (TLOVR) dataset. In the TLOVR dataset, participant responses at a specified threshold of HIV-1 RNA (<50 copies/mL) are determined by using the Food and Drug Administration's TLOVR algorithm. Using the TLOVR algorithm, participants are considered to have failed on therapy if they never achieved confirmed RNA levels below the threshold, if they had confirmed rebound of RNA above the threshold, if they made a non-permitted change in background regimen, or if they permanently discontinued investigational product for any reason. Data are reported per the Week 16 report. In later cuts of the data, the Week 16 values may have changed (because of the nature of the TLOVR algorithm).ITT-E Population included all randomized participants who received at least one dose of study medication	
End point type	Primary
End point timeframe: Week 16	

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: There are no statistical data to report.

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[2]	51	51	50
Units: participants				
participants	51	47	46	29

Notes:

[2] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Viral change over the initial 2 weeks of treatment

End point title	Viral change over the initial 2 weeks of treatment
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End point description:

Plasma samples were collected for quantitative HIV-1 RNA analysis at Baseline and Week 2. Viral change is defined as the change in plasma HIV-1 RNA over the initial 2 weeks of treatment, calculated as the value at Week 2 minus the value at Baseline. Only those participants available at the specified time point were analyzed.

End point type	Secondary
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End point timeframe:

Baseline and Week 2

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[3]	50	50	48
Units: Log10 c/mL				
arithmetic mean (standard deviation)				
Log10 c/mL	-2.387 (± 0.4595)	-2.365 (± 0.5458)	-2.392 (± 0.4241)	-1.930 (± 0.4312)

Notes:

[3] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in HIV-1 RNA at the indicated time points

End point title	Change from Baseline in HIV-1 RNA at the indicated time points
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End point description:

Plasma samples were collected for quantitative HIV-1 RNA analysis at Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[4]	51	51	50
Units: Log ₁₀ c/mL				
arithmetic mean (standard deviation)				
Week 1, n=53, 50, 48, 50	-1.815 (± 0.3999)	-1.773 (± 0.4650)	-1.738 (± 0.3840)	-1.562 (± 0.4158)
Week 2, n=53, 50, 50, 48	-2.387 (± 0.4595)	-2.365 (± 0.5458)	-2.392 (± 0.4241)	-1.930 (± 0.4312)
Week 4, n=53, 50, 50, 45	-2.629 (± 0.5863)	-2.583 (± 0.6337)	-2.713 (± 0.5471)	-2.162 (± 0.5400)
Week 8, n=52, 50, 49, 45	-2.657 (± 0.6980)	-2.666 (± 0.6667)	-2.848 (± 0.6556)	-2.450 (± 0.5989)
Week 12, n=53, 49, 49, 45	-2.685 (± 0.6831)	-2.671 (± 0.6850)	-2.860 (± 0.6772)	-2.603 (± 0.5869)
Week 16, n=52, 49, 49, 45	-2.718 (± 0.6593)	-2.668 (± 0.6826)	-2.859 (± 0.6876)	-2.698 (± 0.6715)
Week 20, n=52, 48, 49, 44	-2.701 (± 0.6423)	-2.662 (± 0.6908)	-2.869 (± 0.6896)	-2.745 (± 0.6602)
Week 24, n=52, 49, 48, 45	-2.700 (± 0.6261)	-2.657 (± 0.6969)	-2.853 (± 0.6889)	-2.773 (± 0.7026)
Week 32, n=52, 49, 47, 45	-2.717 (± 0.6588)	-2.658 (± 0.6991)	-2.855 (± 0.6963)	-2.772 (± 0.7021)
Week 40, n=51, 48, 47, 44	-2.647 (± 0.7039)	-2.665 (± 0.7051)	-2.855 (± 0.6934)	-2.795 (± 0.7169)
Week 48, n=51, 48, 48, 45	-2.723 (± 0.6519)	-2.667 (± 0.6934)	-2.850 (± 0.6849)	-2.711 (± 0.7765)
Week 60, n=50, 48, 48, 44	-2.741 (± 0.6444)	-2.675 (± 0.7012)	-2.825 (± 0.7458)	-2.765 (± 0.7035)
Week 72, n=51, 47, 48, 44	-2.742 (± 0.6453)	-2.622 (± 0.8052)	-2.860 (± 0.6930)	-2.757 (± 0.7094)
Week 84, n=51, 47, 47, 43	-2.725 (± 0.6506)	-2.670 (± 0.7064)	-2.855 (± 0.6923)	-2.743 (± 0.7321)
Week 96, n=48, 44, 46, 39	-2.728 (± 0.6494)	-2.680 (± 0.7116)	-2.854 (± 0.7061)	-2.807 (± 0.7238)

Notes:

[4] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in cluster of differentiation 4+ (CD4+) cell counts at the indicated time points

End point title	Change from Baseline in cluster of differentiation 4+ (CD4+) cell counts at the indicated time points
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End point description:

Blood samples were collected for lymphocyte subset assessment by flow cytometry at Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96. Change from Baseline was calculated as the post-Baseline value minus the value at Baseline. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the ITT-E Population.

End point type	Secondary
End point timeframe:	
Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96	

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[5]	51	51	50
Units: Cells per cubic millimeter				
median (inter-quartile range (Q1-Q3))				
Week 1, n=53, 50, 48, 50	85.0 (18.0 to 134.0)	94.5 (40.0 to 160.0)	75.5 (18.5 to 129.5)	42.5 (-23.0 to 111.0)
Week 2, n=53, 50, 50, 47	75.0 (37.0 to 124.0)	79.0 (27.0 to 138.0)	99.5 (53.0 to 160.0)	55.0 (-10.0 to 132.0)
Week 4, n=53, 50, 50, 45	75.0 (34.0 to 151.0)	89.0 (36.0 to 165.0)	110.0 (46.0 to 170.0)	89.0 (30.0 to 165.0)
Week 8, n=52, 50, 49, 44	118.5 (65.5 to 210.5)	156.5 (93.0 to 226.0)	129.0 (105.0 to 201.0)	104.5 (34.5 to 240.5)
Week 12, n=53, 48, 48, 45	139.0 (96.0 to 284.0)	137.5 (61.0 to 250.0)	171.5 (107.5 to 269.0)	127.0 (58.0 to 186.0)
Week 16, n=52, 49, 49, 44	153.0 (95.0 to 276.0)	176.0 (86.0 to 227.0)	160.0 (94.0 to 227.0)	115.5 (65.5 to 226.0)
Week 20, n=52, 48, 49, 44	163.5 (79.5 to 288.5)	200.0 (103.0 to 316.5)	139.0 (64.0 to 238.0)	136.0 (54.5 to 215.5)
Week 24, n=51, 49, 47, 44	159.0 (97.0 to 233.0)	206.0 (102.0 to 289.0)	167.0 (125.0 to 268.0)	109.5 (66.0 to 229.0)
Week 32, n=50, 48, 47, 44	221.5 (94.0 to 300.0)	195.5 (109.0 to 294.0)	203.0 (125.0 to 282.0)	146.5 (82.5 to 223.5)
Week 40, n=50, 48, 47, 44	205.0 (136.0 to 364.0)	204.5 (157.5 to 346.5)	224.0 (123.0 to 322.0)	171.5 (123.0 to 268.0)
Week 48, n=51, 47, 47, 45	204.0 (127.0 to 384.0)	249.0 (143.0 to 416.0)	223.0 (141.0 to 292.0)	174.0 (91.0 to 292.0)
Week 60, n=51, 48, 47, 43	265.0 (173.0 to 365.0)	278.0 (198.5 to 369.5)	229.0 (166.0 to 306.0)	221.0 (153.0 to 355.0)
Week 72, n=51, 47, 48, 44	236.0 (177.0 to 351.0)	285.0 (186.0 to 427.0)	220.0 (146.0 to 373.0)	195.0 (144.0 to 334.5)
Week 84, n=51, 47, 46, 42	292.0 (222.0 to 408.0)	313.0 (244.0 to 366.0)	280.0 (197.0 to 379.0)	296.5 (187.0 to 400.0)
Week 96, n=48, 44, 46, 39	335.0 (253.5 to 478.5)	391.5 (243.0 to 527.0)	326.0 (236.0 to 451.0)	301.0 (204.0 to 445.0)

Notes:

[5] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with new HIV-associated conditions of the indicated class

End point title	Number of participants with new HIV-associated conditions of the indicated class
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End point description:

HIV-associated conditions were assessed according to the Centers for Disease Control and Prevention (CDC) HIV-1 classification system. Category (CAT) A: one or more of the following conditions (CON),

without any CON listed in Categories B and C: asymptomatic HIV infection, persistent generalized lymphadenopathy, acute (primary) HIV infection with accompanying illness or history of acute HIV infection. CAT B: symptomatic CON that are attributed to HIV infection or are indicative of a defect in cell-mediated immunity; or that are considered by physicians to have a clinical course or to require management that is complicated by HIV infection; and not included among CON listed in clinical CAT C. CAT C: the clinical CON listed in the acquired immunodeficiency syndrome (AIDS) surveillance case definition.

End point type	Secondary
End point timeframe:	
From Baseline up to Week 96	

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[6]	51	51	50
Units: Participants				
Category B	2	0	1	1
Category C	0	0	1	0
Death	1	0	0	0

Notes:

[6] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with the indicated type of HIV-1 disease progression (AIDS or death)

End point title	Number of participants with the indicated type of HIV-1 disease progression (AIDS or death)
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End point description:

Clinical disease progression (CDP) was assessed according to the Centers for Disease Control and Prevention (CDC) HIV-1 classification system. Category (CAT) A: one or more of the following conditions (CON), without any CON listed in Categories B and C: asymptomatic HIV infection, persistent generalized lymphadenopathy, acute (primary) HIV infection with accompanying illness or history of acute HIV infection. CAT B: symptomatic CON that are attributed to HIV infection or are indicative of a defect in cell-mediated immunity; or that are considered by physicians to have a clinical course or to require management that is complicated by HIV infection; and not included among CON listed in clinical CAT C. CAT C: the clinical CON listed in the AIDS surveillance case definition. Indicators of CDP were defined as: CAT A at Baseline (BS) to CAT B event (EV), CAT A at BS to a CAT C EV; CAT B at BS to a CAT C EV; CAT C at BS to a new CAT C EV; or CAT A, B, or C at BS to death.

End point type	Secondary
End point timeframe:	
From Baseline up to Week 96	

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[7]	51	51	50
Units: Participants				
CAT A at Baseline to a CAT C event	0	0	0	0
CAT B at Baseline to a CAT C event	0	0	1	0
CAT C at Baseline to a new CAT C event	0	0	0	0
CAT A, B, or C at Baseline to death	1	0	0	0

Notes:

[7] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with plasma HIV-1 RNA <50 c/mL

End point title	Number of participants with plasma HIV-1 RNA <50 c/mL
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End point description:

Plasma samples were collected for quantitative HIV-1 RNA analysis at Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96. The analysis was performed using the time to loss of virological response (TLOVR) dataset. In the TLOVR dataset, participant responses at a specified threshold of HIV-1 RNA (<50 copies/mL) are determined by using the Food and Drug Administration's TLOVR algorithm. Using the TLOVR algorithm, participants are considered to have failed on therapy if they never achieved confirmed RNA levels below the threshold, if they had confirmed rebound of RNA above the threshold, if they made a non-permitted change in background regimen, or if they permanently discontinued investigational product for any reason.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[8]	51	51	50
Units: Participants				
Baseline	0	0	0	0
Week 1	6	4	4	3
Week 2	22	19	11	6
Week 4	37	35	31	9
Week 8	46	45	43	18
Week 12	50	46	45	25
Week 16	51	46	47	29
Week 20	51	47	47	38
Week 24	51	46	47	41
Week 32	50	45	46	43
Week 40	49	45	46	42
Week 48	48	45	46	40
Week 60	48	44	46	41

Week 72	48	44	45	40
Week 84	47	43	46	38
Week 96	42	40	45	36

Notes:

[8] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with plasma HIV-1 RNA <400 c/mL

End point title	Number of participants with plasma HIV-1 RNA <400 c/mL
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End point description:

Plasma samples were collected for quantitative HIV-1 RNA analysis at Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96. The analysis was performed using the time to loss of virological response (TLOVR) dataset. In the TLOVR dataset, participant responses at a specified threshold of HIV-1 RNA (<400 c/mL) are determined by using the Food and Drug Administration's TLOVR algorithm. Using the TLOVR algorithm, participants are considered to have failed on therapy if they never achieved confirmed RNA levels below the threshold, if they had confirmed rebound of RNA above the threshold, if they made a non-permitted change in background regimen, or if they permanently discontinued investigational product for any reason.

End point type	Secondary
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End point timeframe:

Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[9]	51	51	50
Units: Participants				
Baseline	0	0	0	0
Week 1	25	20	16	15
Week 2	45	45	41	23
Week 4	52	49	48	32
Week 8	52	49	49	41
Week 12	52	49	49	45
Week 16	52	48	49	45
Week 20	52	48	49	45
Week 24	52	47	48	45
Week 32	52	47	48	45
Week 40	50	47	48	45
Week 48	50	47	48	44
Week 60	50	46	48	44
Week 72	50	46	47	43
Week 84	50	45	47	42
Week 96	46	43	46	39

Notes:

[9] - ITT-E Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any adverse event (AE) and any serious adverse events (SAE)

End point title	Number of participants with any adverse event (AE) and any serious adverse events (SAE)
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End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A serious adverse event (SAE) is defined as any untoward medical occurrence that, at any dose: results in death; is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity; or is a congenital anomaly/birth defect. All clinically suspected cases of hypersensitivity reaction to abacavir in participants receiving abacavir/lamivudine were reported as SAEs. Medical or scientific judgment was to have been exercised in other situations. Refer to the general AE/SAE module for a list of AEs (occurring at a frequency threshold $\geq 3\%$) and SAEs.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 96/Early Withdrawal

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[10]	51	51	50
Units: Participants				
Any AE	50	46	46	46
Any SAE	5	5	7	7

Notes:

[10] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with the indicated Grade 1 to Grade 4 treatment-emergent clinical chemistry and hematology toxicities

End point title	Number of participants with the indicated Grade 1 to Grade 4 treatment-emergent clinical chemistry and hematology toxicities
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End point description:

Blood samples were collected for the measurement of clinical chemistry and hematology parameters. Toxicities were graded for severity according to the Division of AIDS (DAIDS) toxicity scales as: Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), or Grade 4 (potentially life threatening).

End point type	Secondary
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End point timeframe:

From Baseline up to Week 96/Early Withdrawal

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53 ^[11]	51	51	50
Units: Participants				
Alanine amino transferase	7	11	3	19
Cholesterol	18	16	13	24
Creatinine kinase	17	6	7	5
Lipase	11	13	11	9
Triglycerides	0	1	2	1
Alkaline phosphatase	1	0	1	10
Amylase	2	3	1	4
Aspartate amino transferase	12	8	6	9
Carbon dioxide content/bicarbonate	28	24	23	30
Creatinine	0	4	0	0
Hypercalcemia	0	0	0	1
Hyperglycaemia	16	15	17	17
Hyperkalemia	0	0	1	1
Hypernatremia	1	1	1	0
Hypocalcemia	4	5	5	8
Hypoglycaemia	3	3	5	4
Hypokalemia	4	1	3	3
Hyponatremia	6	12	7	13
Low-density lipoprotein cholesterol	14	15	11	20
Magnesium	7	6	5	4
Phosphate, inorganic	9	15	14	11
Total bilirubin	3	4	3	0
Activated partial thromboplastin time	7	12	6	5
Hemoglobin	0	1	0	1
International normalized ratio	6	9	6	5
Platelet count	1	4	1	1
Prothrombin time	7	8	7	4
Total neutrophils	9	7	6	10
White blood cell count	1	1	1	1

Notes:

[11] - Safety Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with the indicated treatment-emergent integrase (IN) mutations detected at the time of protocol-defined virologic failure (PDVF), as a measure of genotypic resistance

End point title	Number of participants with the indicated treatment-emergent integrase (IN) mutations detected at the time of protocol-defined virologic failure (PDVF), as a measure of genotypic
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End point description:

For participants meeting one of the criteria for PDVF, plasma samples collected at the time point of virologic failure were tested to evaluate any potential genotypic and/or phenotypic evolution of resistance. PDVF was defined as (A) Virologic Non-response: a decrease in plasma HIV-1 RNA of <1 log₁₀ copies/mL by Week 4, with subsequent confirmation, unless plasma HIV-1 RNA is <400 copies/mL; confirmed plasma HIV-1 RNA levels ≥400 copies/mL on or after Week 24 without evidence of prior suppression to <400copies/mL or (B) Virologic Rebound: confirmed rebound in plasma HIV-1 RNA levels to ≥400 copies/mL after prior confirmed suppression to <400 copies/mL; confirmed plasma HIV-1 RNA levels >0.5 log₁₀ copies/mL above the nadir value, where nadir is the lowest HIV-1 value ≥400 copies/mL. On-treatment Genotypic Resistance Population: all participants in the ITT-E Population with available on-treatment genotypic data, excluding participants who were not protocol-defined virologic failures.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 96/Early Withdrawal

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	0 ^[12]	1
Units: Participants				
A23A/V	1	0		0
S255N	1	0		0

Notes:

[12] - On-treatment Genotypic Resistance Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with the indicated treatment-emergent major mutations of other classes detected at the time of protocol-defined virologic failure (PDVF), as a measure of genotypic resistance

End point title	Number of participants with the indicated treatment-emergent major mutations of other classes detected at the time of protocol-defined virologic failure (PDVF), as a measure of genotypic resistance
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End point description:

For participants meeting one of the criteria for PDVF, plasma samples collected at the time point of virologic failure were tested to evaluate any potential genotypic and/or phenotypic evolution of resistance. PDVF was defined as (A) Virologic Non-response: a decrease in plasma HIV-1 RNA of <1 log₁₀ copies/mL by Week 4, with subsequent confirmation, unless plasma HIV-1 RNA is <400 copies/mL; confirmed plasma HIV-1 RNA levels ≥400 copies/mL on or after Week 24 without evidence of prior suppression to <400copies/mL or (B) Virologic Rebound: confirmed rebound in plasma HIV-1 RNA levels to ≥400 copies/mL after prior confirmed suppression to <400 copies/mL; confirmed plasma HIV-1 RNA levels >0.5 log₁₀ copies/mL above the nadir value, where nadir is the lowest HIV-1 value ≥400 copies/mL.

End point type	Secondary
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End point timeframe:

From Baseline up to Week 96/Early Withdrawal

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	0 ^[13]	1
Units: Participants				
Participants	1	0		0

Notes:

[13] - On-treatment Genotypic Resistance Population

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with the indicated fold increase in DTG FC (fold change in IC50 relative to wild-type virus) at the time of PDVF, as a measure of post-Baseline phenotypic resistance

End point title	Number of participants with the indicated fold increase in DTG FC (fold change in IC50 relative to wild-type virus) at the time of PDVF, as a measure of post-Baseline phenotypic resistance
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End point description:

The FC in IC50 (50% inhibitory concentration) for DTG relative to wild-type virus was determined for virus isolated at Baseline and at the time of PDVF. Fold increase in DTG FC at the time of PDVF was derived as the PDVF FC/Baseline FC ratio. PDVF was defined as (A) Virologic Non-response: a decrease in plasma HIV-1 RNA of <1 log10 copies/mL by Week 4, with subsequent confirmation, unless plasma HIV-1 RNA is <400 copies/mL; confirmed plasma HIV-1 RNA levels ≥400 copies/mL on or after Week 24 without evidence of prior suppression to <400copies/mL or (B) Virologic Rebound: confirmed rebound in plasma HIV-1 RNA levels to ≥400 copies/mL after prior confirmed suppression to <400 copies/mL; confirmed plasma HIV-1 RNA levels >0.5 log10 copies/mL above the nadir value, where nadir is the lowest HIV-1 value ≥400 copies/mL. On-treatment Phenotypic Resistance Population: all participants in the ITT-E Population with available on-treatment phenotypic data

End point type	Secondary
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End point timeframe:

From Baseline up to Week 96/Early Withdrawal

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	0 ^[14]	0 ^[15]
Units: Participants				
<1 fold	0	1		
1-<2 fold	2	0		
2-<4 fold	0	0		
4-<8 fold	0	0		
≥8 fold	0	0		

Notes:

[14] - On-treatment Phenotypic Resistance Population

[15] - On-treatment Phenotypic Resistance Population

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma DTG concentration

End point title	Plasma DTG concentration
End point description:	
Blood samples for the determination of plasma DTG concentration were collected from the participants randomized to receive DTG, at the following time points: pre-dose and 2-4 hours post-dose at Weeks 2, Week 12, and Week 24. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed. The Pharmacokinetic (PK) Summary Population is comprised of all participants who received DTG and underwent intensive PK sampling or limited PK sampling during the study and provided evaluable DTG PK parameters. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the PK Summary Population.	
End point type	Secondary
End point timeframe:	
Week 2, Week 12, and Week 24	

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	46	46	0 ^[16]
Units: Micrograms per milliliter (µg/mL)				
arithmetic mean (standard deviation)				
Week 2, Pre-dose, n=46, 44, 43, 0	0.3580 (± 0.18321)	0.6779 (± 0.44085)	1.4044 (± 0.88041)	()
Week 2, 2-4 hours post-dose, n=31, 29, 29, 0	1.0121 (± 0.28125)	1.9716 (± 0.71890)	3.8414 (± 1.87405)	()
Week 12, Pre-dose, n= 46, 45, 44, 0	0.3648 (± 0.16791)	0.5759 (± 0.32645)	1.4169 (± 1.00152)	()
Week 12, 2-4 hours post-dose, n=48, 45, 45, 0	1.0374 (± 0.27517)	1.7907 (± 0.70953)	3.6056 (± 1.33862)	()
Week 24, Pre-dose, n=45, 44, 44, 0	0.3766 (± 0.23399)	0.6636 (± 0.50767)	1.4534 (± 0.94283)	()
Week 24, 2-4 hours post-dose, n=45, 45, 45, 0	1.0113 (± 0.34083)	1.9021 (± 0.79430)	3.5397 (± 1.36538)	()

Notes:

[16] - PK Summary Population.

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-tau) of DTG

End point title	AUC(0-tau) of DTG
End point description:	
The area under the time concentration curve over the dosing interval (AUC[0-tau]) of DTG was determined using non-compartmental analysis based on intensive PK sampling at the following time points: pre-dose; 2, 3, 4, 8, and 24 hours post-dose at Week 2. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed. Only those participants available at the specified time points were analyzed.	
End point type	Secondary
End point timeframe:	
Pre-dose and 2, 3, 4, 8, and 24 hours post-dose at Week 2	

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	15	0 ^[17]
Units: Hours*µg/mL				
geometric mean (geometric coefficient of variation)				
Hours*µg/mL	16.0 (± 40)	23.1 (± 48)	48.1 (± 40)	()

Notes:

[17] - PK Summary Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximal concentration (C_{max}), minimal concentration (C_{min}), and concentration at the end of dosing interval (C_{tau}) of DTG

End point title	Maximal concentration (C _{max}), minimal concentration (C _{min}), and concentration at the end of dosing interval (C _{tau}) of DTG
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End point description:

The C_{max}, C_{min}, and C_{tau} of DTG were determined using non-compartmental analysis based on intensive PK sampling at the following time points: pre-dose; 2, 3, 4, 8, and 24 hours post-dose at Week 2. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed.

End point type	Secondary
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End point timeframe:

Pre-dose and 2, 3, 4, 8, and 24 hours post-dose at Week 2

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	15	0 ^[18]
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
C _{max}	1.10 (± 37)	1.71 (± 43)	3.40 (± 27)	()
C _{min}	0.33 (± 64)	0.44 (± 68)	0.94 (± 74)	()
C _{tau}	0.37 (± 55)	0.45 (± 71)	1.05 (± 72)	()

Notes:

[18] - PK Summary Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Pre-dose concentration (C₀) and C₀ avg of DTG

End point title	Pre-dose concentration (C ₀) and C ₀ avg of DTG
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End point description:

The plasma DTG C0 of DTG was determined using limited/sparse PK sampling at Week 2, Week 12, and Week 24. C0 avg was calculated at Week 24 as the mean of the C0 of DTG at Week 2, Week 12, and Week 24. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed. Only those participants available at the specified time points were analyzed (represented by n=X, X, X, X in the category titles). Different participants may have been analyzed at different time points, so the overall number of participants analyzed reflects everyone in the PK Summary Population.

End point type	Secondary
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End point timeframe:

Week 2, Week 12, and Week 24

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	46	46	0 ^[19]
Units: Microgram per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)				
C0, Week 2, n=46, 44, 43, 0	0.31 (± 58)	0.57 (± 62)	1.20 (± 61)	()
C0, Week 12, n=46, 45, 44, 0	0.33 (± 49)	0.47 (± 77)	1.13 (± 95)	()
C0, Week 24, n=45, 44, 44, 0	0.33 (± 67)	0.57 (± 74)	1.20 (± 74)	()
C0 avg, n=48, 46, 46, 0	0.34 (± 49)	0.56 (± 61)	1.25 (± 55)	()

Notes:

[19] - PK Summary Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to maximal drug concentration (tmax) of DTG

End point title	Time to maximal drug concentration (tmax) of DTG
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End point description:

Tmax of DTG was determined using non-compartmental analysis based on intensive PK sampling at the following time points: pre-dose; 2, 3, 4, 8, and 24 hours post-dose at Week 2. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed.

End point type	Secondary
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End point timeframe:

Pre-dose and 2, 3, 4, 8, and 24 hours post-dose at Week 2

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	15	0 ^[20]
Units: Hours				
median (full range (min-max))				
Hours	2.0 (2.0 to 4.0)	2.0 (2.0 to 8.0)	2.0 (1.9 to 4.0)	(to)

Notes:

[20] - PK Summary Population.

Statistical analyses

No statistical analyses for this end point

Secondary: Relationship between the change from Baseline in plasma HIV-1 RNA at Week 2 and the indicated plasma DTG PK parameters

End point title	Relationship between the change from Baseline in plasma HIV-1 RNA at Week 2 and the indicated plasma DTG PK parameters
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End point description:

Relationships between Week 2 plasma DTG PK parameters (AUC[0-tau] [area under the time concentration curve over the dosing interval], Cmax [maximal concentration], and Ctau [concentration at the end of the dosing interval]) and the change from Baseline in plasma HIV-1 RNA at Week 2 (calculated as the post-Baseline value minus the value at Baseline) was assessed using Pearson's correlation analyses. The Pearson's correlation coefficient is a measure of the correlation between plasma HIV-1 RNA and plasma DTG PK parameters and ranges from -1 to 1. A value of 0 indicates no statistical association; a value close to -1 or 1 indicates a higher association. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed. PK/Pharmacodynamic (PD) Analysis Population: all participants with available PD measures (e.g., safety and/or efficacy data) and with evaluable DTG plasma concentration data considered suitable for investigation of relationship with the PD measures

End point type	Secondary
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End point timeframe:

Week 2

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	15	0 ^[21]
Units: Pearson's correlation coefficient				
number (not applicable)				
AUC(0-tau)	0.426	-0.018	-0.258	
Cmax	0.452	-0.051	-0.150	
Ctau	0.273	-0.100	-0.263	

Notes:

[21] - PK/PD Analysis Population.

End point values	Overall DTG			
Subject group type	Subject analysis set			
Number of subjects analysed	45			
Units: Pearson's correlation coefficient				
number (not applicable)				
AUC(0-tau)	-0.086			
Cmax	-0.055			
Ctau	-0.129			

Statistical analyses

No statistical analyses for this end point

Secondary: Relationship between the change from Baseline in CD4+ cell counts at Week 96 and the indicated plasma DTG PK parameters

End point title	Relationship between the change from Baseline in CD4+ cell counts at Week 96 and the indicated plasma DTG PK parameters
End point description:	
Relationships between plasma DTG PK parameters (AUC[0-tau] [area under the time concentration curve over the dosing interval], Cmax [maximal concentration], C0avg [average pre-dose concentration], and Ctau [concentration at the end of the dosing interval]) and the change from Baseline in CD4+ cell counts at Week 96 (calculated as the post-Baseline value minus the value at Baseline) was assessed using Pearson's correlation analyses. The Pearson's correlation coefficient is a measure of the correlation between CD4+ cell counts and plasma DTG PK parameters and ranges from -1 to 1. A value of 0 indicates no statistical association; a value close to -1 or 1 indicates a higher association. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed. Only those participants available at the specified time points were analyzed (represented by n=X in the category titles)	
End point type	Secondary
End point timeframe:	
Week 96	

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	46	46	0 ^[22]
Units: Pearson's correlation coefficient				
number (not applicable)				
AUC(0-tau), n=13, 14, 15, 0	-0.100	0.379	0.008	
Cmax, n=13, 14, 15, 0	-0.047	0.332	0.234	
C0avg, n=43, 40, 42, 0	-0.009	-0.013	0.206	
Ctau, n=13, 14, 15, 0	-0.289	0.299	-0.074	

Notes:

[22] - PK/PD Analysis Population.

End point values	Overall DTG			
Subject group type	Subject analysis set			
Number of subjects analysed	142			
Units: Pearson's correlation coefficient				
number (not applicable)				
AUC(0-tau), n=13, 14, 15, 0	-0.005			
Cmax, n=13, 14, 15, 0	0.037			
C0avg, n=43, 40, 42, 0	-0.011			

Ctau, n=13, 14, 15, 0	-0.055			
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Statistical analyses

No statistical analyses for this end point

Secondary: Relationship between the indicated safety parameters at Week 96 and the indicated plasma DTG PK parameters

End point title	Relationship between the indicated safety parameters at Week 96 and the indicated plasma DTG PK parameters
End point description:	
Relationships between log-transformed plasma DTG PK parameters (AUC[0-tau], Cmax, C0, C0avg, Ctau, and Cmin) and safety parameters (AE occurrence, maximum AE intensity, alanine aminotransferase [ALT], change from Baseline [CFB] in ALT, total bilirubin, CFB in total bilirubin, creatine kinase, CFB in creatine kinase, triglycerides, CFB in triglycerides, lipase, CFB in lipase, total cholesterol [TC], CFB in TC) was assessed using Pearson's correlation analyses. The Pearson's correlation coefficient is a measure of the correlation between safety parameters and plasma DTG PK parameters and ranges from -1 to 1. A value of 0 indicates no statistical association; a value close to -1 or 1 indicates a higher association. The presence of ≥ 1 AE was used for AE occurrence. The most severe AE grade/intensity was used for maximum AE intensity. Maximum laboratory values per participant were used for safety parameters. CFB was calculated as the post-Baseline value minus the value at Baseline.	
End point type	Secondary
End point timeframe:	
Week 96	

End point values	Overall DTG			
Subject group type	Subject analysis set			
Number of subjects analysed	142			
Units: Pearson's correlation coefficient				
number (not applicable)				
AUC(0-tau) versus AE occurrence, n=45	0.114			
AUC(0-tau) versus maximum AE intensity, n=45	0.171			
AUC(0-tau) versus ALT, n=45	-0.196			
AUC(0-tau) versus CFB in ALT, n=45	-0.201			
AUC(0-tau) versus total bilirubin, n=45	0.364			
AUC(0-tau) versus CFB in total bilirubin, n=45	0.147			
AUC(0-tau) versus creatine kinase, n=45	-0.168			
AUC(0-tau) versus CFB in creatine kinase, n=45	-0.145			
AUC(0-tau) vs Triglycerides, n=45	0.104			
AUC(0-tau) versus CFB in triglycerides, n=45	0.216			
AUC(0-tau) versus lipase, n=45	-0.066			
AUC(0-tau) versus CFB in lipase, n=45	0.092			

AUC(0-tau) versus total cholesterol, n=45	-0.097			
AUC(0-tau) versus CFB in total cholesterol, n=45	-0.153			
Cmax versus AE occurrence, n=45	0.061			
Cmax versus maximum AE intensity, n=45	0.110			
Cmax versus ALT, n=45	-0.135			
Cmax versus CFB in ALT, n=45	-0.135			
Cmax versus total bilirubin, n=45	0.265			
Cmax versus CFB in total bilirubin, n=45	0.033			
Cmax versus creatine kinase, n=45	-0.188			
Cmax versus CFB in creatine kinase, n=45	-0.161			
Cmax versus triglycerides, n=45	0.134			
Cmax versus CFB in triglycerides, n=45	0.244			
Cmax versus lipase, n=45	-0.034			
Cmax versus CFB in lipase, n=45	0.115			
Cmax versus total cholesterol, n=45	-0.101			
Cmax versus CFB in total cholesterol, n=45	-0.192			
C0 versus AE occurrence, n=133	-0.080			
C0 versus maximum AE intensity, n=133	-0.003			
C0 versus ALT, n=133	-0.196			
C0 versus CFB in ALT, n=133	-0.237			
C0 versus total bilirubin, n=133	0.298			
C0 versus CFB in total bilirubin, n=133	0.120			
C0 versus creatine kinase, n=133	-0.094			
C0 versus CFB in creatine kinase, n=133	-0.093			
C0 versus triglycerides, n=133	-0.058			
C0 versus CFB in triglycerides, n=133	-0.012			
C0 versus lipase, n=133	-0.187			
C0 versus CFB in lipase, n=133	-0.137			
C0 versus total cholesterol, n=133	-0.179			
C0 versus CFB in total cholesterol, n=133	-0.125			
C0avg versus AE occurrence, n=140	-0.028			
C0avg versus maximum AE intensity, n=140	0.036			
C0avg versus ALT, n=140	-0.166			
C0avg versus CFB in ALT, n=140	-0.177			
C0avg versus total bilirubin, n=140	0.319			
C0avg versus CFB in total bilirubin, n=140	0.109			
C0avg versus creatine kinase, n=140	-0.114			
C0avg versus CFB in creatine kinase, n=140	-0.110			
C0avg versus triglycerides, n=140	0.057			
C0avg versus CFB in triglycerides, n=140	0.092			
C0avg versus lipase, n=140	-0.164			
C0avg versus CFB in lipase, n=140	-0.120			
C0avg versus total cholesterol, n=140	-0.170			

C0avg versus CFB in total cholesterol, n=140	-0.083			
Ctau versus AE occurrence, n=45	0.190			
Ctau versus maximum AE intensity, n=45	0.205			
Ctau versus ALT, n=45	-0.281			
Ctau versus CFB in ALT, n=45	-0.285			
Ctau versus total bilirubin, n=45	0.446			
Ctau versus CFB in total bilirubin, n=45	0.237			
Ctau versus creatine kinase, n=45	-0.143			
Ctau versus CFB in creatine kinase, n=45	-0.125			
Ctau versus triglycerides, n=45	0.061			
Ctau versus CFB in triglycerides, n=45	0.172			
Ctau versus lipase, n=45	-0.131			
Ctau versus CFB in lipase, n=45	0.056			
Ctau versus total cholesterol, n=45	-0.039			
Ctau versus CFB in total cholesterol, n=45	-0.108			
Cmin versus AE occurrence, n=45	0.156			
Cmin versus maximum AE intensity, n=45	0.193			
Cmin versus ALT, n=45	-0.236			
Cmin versus CFB in ALT, n=45	-0.253			
Cmin versus total bilirubin, n=45	0.430			
Cmin versus CFB in total bilirubin, n=45	0.171			
Cmin versus creatine kinase, n=45	-0.132			
Cmin versus CFB in creatine kinase, n=45	-0.124			
Cmin versus triglycerides, n=45	-0.042			
Cmin versus CFB in triglycerides, n=45	0.057			
Cmin versus lipase, n=45	-0.135			
Cmin versus CFB in lipase, n=45	0.032			
Cmin versus total cholesterol, n=45	-0.194			
Cmin versus CFB in total cholesterol, n=45	-0.208			

Statistical analyses

No statistical analyses for this end point

Secondary: Relationship between gastrointestinal system organ class AEs of special interest at Week 96 and the indicated plasma DTG PK parameters

End point title	Relationship between gastrointestinal system organ class AEs of special interest at Week 96 and the indicated plasma DTG PK parameters
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End point description:

Logistic regressions were performed to examine the correlation between plasma DTG PK parameters (AUC[0-tau] [area under the time concentration curve over the dosing interval], Cmax [maximal concentration], Ctau [concentration at the end of the dosing interval], and C0avg [average pre-dose concentration]) on log scales and the presence of gastrointestinal system organ class AEs (abdominal pain, diarrhea, nausea, and vomiting) at Week 96. Data are presented as estimates from logistic regression, which is a measure of the association between AEs of special interest and plasma DTG PK parameters. A value of 0 indicates no statistical association; a large absolute value of the estimate

indicates higher association. Because PK was assessed for DTG, no participants in the EFV treatment group were analyzed. Results are presented for participants in any DTG group (overall DTG). Only those participants available at the specified time points were analyzed represented by n=X in the category titles

End point type	Secondary
End point timeframe:	
Week 96	

End point values	Overall DTG			
Subject group type	Subject analysis set			
Number of subjects analysed	142 ^[23]			
Units: estimated effect				
number (not applicable)				
Abdominal pain versus AUC(0-tau), n=45	-2.49			
Abdominal pain versus Cmax, n=45	-2.98			
Abdominal pain versus Ctau, n=45	-1.72			
Abdominal pain versus C0avg, n=140	-0.41			
Diarrhoea versus AUC(0-tau), n=45	-0.62			
Diarrhoea versus Cmax, n=45	-0.98			
Diarrhoea versus Ctau, n=45	-0.29			
Diarrhoea versus C0avg, n=140	0.13			
Nausea versus AUC(0-tau), n=45	-0.31			
Nausea versus Cmax, n=45	-0.72			
Nausea versus Ctau, n=45	0.03			
Nausea versus C0avg, n=140	-0.32			
Vomiting versus AUC(0-tau), n=45	-1.29			
Vomiting versus Cmax, n=45	-1.61			
Vomiting versus Ctau, n=45	-1.15			
Vomiting versus C0avg, n=140	-0.89			

Notes:

[23] - PK/PD Analysis Population.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Change from Baseline in cluster of differentiation 8+ (CD8+) cell counts at the indicated time points

End point title	Change from Baseline in cluster of differentiation 8+ (CD8+) cell counts at the indicated time points
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End point description:

Change from Baseline in CD8+ cell count data are not available; CD8+ data are only listed on a per-participant basis and were not summarized.

End point type	Other pre-specified
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End point timeframe:

Baseline (Day 1), Week 1, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 32, Week 40, Week 48, Week 60, Week 72, Week 84, and Week 96

End point values	DTG 10 mg QD	DTG 25 mg QD	DTG 50 mg QD	EFV 600 mg QD
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[24]	0 ^[25]	0 ^[26]	0 ^[27]
Units: Cells per cubic millimeter				
median (inter-quartile range (Q1-Q3))				
Cells per cubic millimeter	(to)	(to)	(to)	(to)

Notes:

[24] - ITT-E Population.

[25] - ITT-E Population.

[26] - ITT-E Population.

[27] - ITT-E Population.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events (SAEs) and non-serious AEs were collected in the time period from Baseline up to end of study.

Adverse event reporting additional description:

SAEs and AEs were collected in members of Safety Population, comprised of all participants who received at least one dose of study medication.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	20.0
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Reporting groups

Reporting group title	DTG 10mg QD
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Reporting group description:

Participants received DTG 10 mg, DTG matching placebo, and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.

Reporting group title	DTG 25mg QD
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Reporting group description:

Participants received DTG 25 mg, DTG matching placebo, and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.

Reporting group title	DTG 50mg QD
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Reporting group description:

Participants received DTG 50 mg and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.

Reporting group title	EFV 600mg
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Reporting group description:

Participants received Efavirenz (EFV) 600 mg and ABC/3TC 600 mg/300 mg or TDF/FTC 300 mg/200 mg orally QD for 96 weeks.

Reporting group title	Open-label DTG 50 mg QD
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Reporting group description:

All DTG participants were switched to or continued DTG 50 mg with either ABC/3TC orally at 600 mg/300 mg (1 tablet) or TDF/FTC orally QD during the Open label phase

Serious adverse events	DTG 10mg QD	DTG 25mg QD	DTG 50mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 53 (11.32%)	4 / 51 (7.84%)	7 / 51 (13.73%)
number of deaths (all causes)	2	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Burkitt's lymphoma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
Phlebitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Dysmenorrhoea			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device malfunction			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Wrist fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Joint dislocation			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (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
Multiple injuries			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Spinal compression fracture subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Headache subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (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
Hydrocephalus subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Constipation subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (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
Flatulence			

subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (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
Inguinal hernia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (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
Nausea			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Cholelithiasis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (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			
Back pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Tendonitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (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
Appendicitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epididymitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
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 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurosyphilis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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 pneumococcal			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (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
Primary syphilis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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			
Lipomatosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
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	EFV 600mg	Open-label DTG 50 mg QD	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 50 (14.00%)	16 / 138 (11.59%)	
number of deaths (all causes)	0	2	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Burkitt's lymphoma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Phlebitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			

Anxiety			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device malfunction			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 2	
Injury, poisoning and procedural complications			
Wrist fracture			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	

Joint dislocation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple injuries			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hydrocephalus			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Seizure			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flatulence			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mallory-Weiss syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendonitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Epididymitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurosyphilis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumococcal sepsis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary syphilis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			

subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Lipomatosis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obesity			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	DTG 10mg QD	DTG 25mg QD	DTG 50mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 53 (92.45%)	46 / 51 (90.20%)	45 / 51 (88.24%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	4	0	1
Melanocytic naevus			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Infected naevus			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Papilloma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Prostatic adenoma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			

subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	0	2	0
Aortic arteriosclerosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Arterial fibrosis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Peripheral venous disease			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	5 / 53 (9.43%)	4 / 51 (7.84%)	1 / 51 (1.96%)
occurrences (all)	5	4	1
Fatigue			
subjects affected / exposed	2 / 53 (3.77%)	4 / 51 (7.84%)	2 / 51 (3.92%)
occurrences (all)	2	7	2
Asthenia			
subjects affected / exposed	4 / 53 (7.55%)	2 / 51 (3.92%)	1 / 51 (1.96%)
occurrences (all)	4	3	1
Influenza like illness			

subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	1	0	2
Chest pain			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Malaise			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Adverse drug reaction			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Drug intolerance			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Feeling drunk			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Nodule			

subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Oedema subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Immune system disorders			
Seasonal allergy subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	2 / 51 (3.92%) 2	1 / 51 (1.96%) 1
Allergy to arthropod sting subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Drug hypersensitivity subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Food allergy subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Hypersensitivity subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Multiple allergies subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 2	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Reproductive system and breast disorders			
Erectile dysfunction subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	0 / 51 (0.00%) 0	2 / 51 (3.92%) 2
Genital lesion subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Ovarian cyst subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Prostatitis			

subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Breast discomfort			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Breast mass			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Cervical dysplasia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gynaecomastia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Penile discharge			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Peyronie's disease			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 53 (9.43%)	4 / 51 (7.84%)	6 / 51 (11.76%)
occurrences (all)	5	4	8
Oropharyngeal pain			
subjects affected / exposed	3 / 53 (5.66%)	0 / 51 (0.00%)	3 / 51 (5.88%)
occurrences (all)	3	0	3
Asthma			
subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	1 / 51 (1.96%)
occurrences (all)	1	3	1
Sinus congestion			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	0	1	2
Dyspnoea			

subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	1 / 51 (1.96%)
occurrences (all)	0	2	1
Rhinitis allergic			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	2	1
Lung disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Respiratory disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Asthmatic crisis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Bronchitis chronic			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Bronchopneumopathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Hyperventilation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract congestion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Pharyngeal disorder			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Respiratory tract congestion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Sleep apnoea syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Snoring			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract congestion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 53 (0.00%)	7 / 51 (13.73%)	6 / 51 (11.76%)
occurrences (all)	0	7	6
Depression			
subjects affected / exposed	3 / 53 (5.66%)	6 / 51 (11.76%)	2 / 51 (3.92%)
occurrences (all)	3	6	3
Anxiety			
subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	2 / 51 (3.92%)
occurrences (all)	2	2	2
Abnormal dreams			
subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	1	2	0
Nightmare			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	0	1	2

Acute stress disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Loss of libido			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Sleep disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Affect lability			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Anxiety disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bulimia nervosa			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Disorientation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Libido increased			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Listless			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Mental disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Panic attack			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Post-traumatic stress disorder subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Substance use disorder subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Investigations			
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	3 / 51 (5.88%) 3	0 / 51 (0.00%) 0
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	1 / 51 (1.96%) 1
Blood glucose increased subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Amylase increased subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Anal pap smear abnormal subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Bacterial test positive subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Cardiac murmur			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram repolarisation abnormality			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Urinary sediment present			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Laceration			

subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	0	2	0
Limb injury			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Procedural pain			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Anal injury			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Cervical vertebral fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Clavicle fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Face injury			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Rib fracture			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Scrotal haematoma			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Vaccination complication			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Wrist fracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Aortic valve incompetence			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Arrhythmia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Cardiomegaly			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0

Palpitations subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Nervous system disorders			
Headache subjects affected / exposed occurrences (all)	7 / 53 (13.21%) 9	6 / 51 (11.76%) 10	8 / 51 (15.69%) 12
Dizziness subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	3 / 51 (5.88%) 4	3 / 51 (5.88%) 3
Paraesthesia subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 3	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Somnolence subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	1 / 51 (1.96%) 1	1 / 51 (1.96%) 1
Dysgeusia subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Memory impairment subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	0 / 51 (0.00%) 0	1 / 51 (1.96%) 2
Sciatica subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Hypoaesthesia subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Poor quality sleep subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Restless legs syndrome subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Syncope			

subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Ageusia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Anosmia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Cervical radiculopathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Cluster headache			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Cognitive disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Hypertonia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Post herpetic neuralgia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sinus headache			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Tongue biting			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Trigeminal neuralgia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Visual field defect			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	2 / 53 (3.77%)	3 / 51 (5.88%)	0 / 51 (0.00%)
occurrences (all)	2	3	0
Neutropenia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Lymphadenitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	2	1	2
Tinnitus			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Ear pain			

subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	0	2	0
Hypoacusis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Cerumen impaction			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear congestion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Ear pruritus			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Presbycusis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Astigmatism			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Chalazion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Dark circles under eyes			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Myopia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Visual acuity reduced			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Vitreous floaters subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	6 / 53 (11.32%) 6	9 / 51 (17.65%) 10	7 / 51 (13.73%) 8
Nausea subjects affected / exposed occurrences (all)	10 / 53 (18.87%) 10	8 / 51 (15.69%) 9	6 / 51 (11.76%) 6
Haemorrhoids subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	2 / 51 (3.92%) 2
Abdominal pain subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 3	1 / 51 (1.96%) 1	2 / 51 (3.92%) 2
Dyspepsia subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	2 / 51 (3.92%) 3	2 / 51 (3.92%) 2
Abdominal pain upper subjects affected / exposed occurrences (all)	4 / 53 (7.55%) 5	3 / 51 (5.88%) 3	1 / 51 (1.96%) 1
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 3	3 / 51 (5.88%) 3	0 / 51 (0.00%) 0
Toothache subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	2 / 51 (3.92%) 2	1 / 51 (1.96%) 2
Gastritis subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Abdominal discomfort			

subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	2	1	1
Constipation			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	3	1	0
Proctitis			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Faeces soft			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Haematochezia			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Anal fissure			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Anal fistula			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Anogenital dysplasia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Aphthous ulcer			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	4	0	0
Epigastric discomfort			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Flatulence			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	3	0
Inguinal hernia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Abdominal pain lower			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Anal pruritus			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Anal skin tags			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Anal sphincter hypertonia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Anal ulcer			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Anorectal disorder			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Anorectal ulcer			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Change of bowel habit			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Chronic gastritis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Dental caries			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Enteritis			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Enterocolitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Hiatus hernia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Intestinal polyp			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Leukoplakia oral			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Odynophagia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Pancreatic atrophy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Perianal erythema			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Rectal polyp			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Stomatitis			

subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Tongue discolouration			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Tongue disorder			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Hepatic steatosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	5 / 53 (9.43%)	3 / 51 (5.88%)	2 / 51 (3.92%)
occurrences (all)	6	3	2
Pruritus			
subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	3	0	1
Dermatitis			
subjects affected / exposed	0 / 53 (0.00%)	3 / 51 (5.88%)	1 / 51 (1.96%)
occurrences (all)	0	3	1
Alopecia			
subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	2	0	1
Eczema			

subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	1	1	1
Night sweats			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	1	1	2
Urticaria			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Erythema			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	2
Hyperhidrosis			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Dry skin			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Hyperkeratosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Prurigo			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Actinic keratosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Blister			

subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Dermal cyst			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Hand dermatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Intertrigo			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Lipoatrophy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Miliaria			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Palmar erythema			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Pigmentation disorder			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Pruritus generalised			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Rash papular			

subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Rash pruritic			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin erosion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Solar dermatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Toxic skin eruption			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Proteinuria			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	1 / 51 (1.96%)
occurrences (all)	0	2	1
Nephrolithiasis			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	2	1	0
Haematuria			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Leukocyturia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1

Acute kidney injury subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Chronic kidney disease subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Micturition urgency subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Urethral discharge subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Urethritis noninfective subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Urinary hesitation subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Endocrine disorders Hypogonadism subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	0 / 51 (0.00%) 0	1 / 51 (1.96%) 1
Hypothyroidism subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Goitre subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Musculoskeletal and connective tissue disorders Back pain subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 4	2 / 51 (3.92%) 2	2 / 51 (3.92%) 2
Arthralgia subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	3 / 51 (5.88%) 3	2 / 51 (3.92%) 2
Musculoskeletal pain			

subjects affected / exposed	1 / 53 (1.89%)	2 / 51 (3.92%)	3 / 51 (5.88%)
occurrences (all)	1	2	3
Myalgia			
subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	2	0	2
Muscle spasms			
subjects affected / exposed	0 / 53 (0.00%)	4 / 51 (7.84%)	0 / 51 (0.00%)
occurrences (all)	0	5	0
Exostosis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	1	0	2
Pain in extremity			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	1 / 51 (1.96%)
occurrences (all)	0	2	1
Tendonitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Facet joint syndrome			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Osteopenia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Plantar fasciitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Ankle impingement			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Chondropathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fistula			

subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Muscle contracture			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Muscle haemorrhage			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Myosclerosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Patellofemoral pain syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Rheumatoid arthritis			

subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	1 / 51 (1.96%) 1	0 / 51 (0.00%) 0
Rotator cuff syndrome subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Synovitis subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Temporomandibular joint syndrome subjects affected / exposed occurrences (all)	0 / 53 (0.00%) 0	0 / 51 (0.00%) 0	0 / 51 (0.00%) 0
Infections and infestations			
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	7 / 53 (13.21%) 10	7 / 51 (13.73%) 10	6 / 51 (11.76%) 10
Bronchitis subjects affected / exposed occurrences (all)	5 / 53 (9.43%) 7	2 / 51 (3.92%) 3	2 / 51 (3.92%) 3
Influenza subjects affected / exposed occurrences (all)	5 / 53 (9.43%) 5	5 / 51 (9.80%) 6	4 / 51 (7.84%) 4
Syphilis subjects affected / exposed occurrences (all)	1 / 53 (1.89%) 1	3 / 51 (5.88%) 3	1 / 51 (1.96%) 1
Respiratory tract infection subjects affected / exposed occurrences (all)	4 / 53 (7.55%) 6	1 / 51 (1.96%) 2	2 / 51 (3.92%) 3
Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 2	3 / 51 (5.88%) 4	6 / 51 (11.76%) 8
Sinusitis subjects affected / exposed occurrences (all)	2 / 53 (3.77%) 3	2 / 51 (3.92%) 3	3 / 51 (5.88%) 4
Pharyngitis subjects affected / exposed occurrences (all)	3 / 53 (5.66%) 3	3 / 51 (5.88%) 3	1 / 51 (1.96%) 1

Gastroenteritis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	2 / 51 (3.92%)
occurrences (all)	0	1	2
Rhinitis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	1	0	2
Tonsillitis			
subjects affected / exposed	3 / 53 (5.66%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	10	1	0
Oral herpes			
subjects affected / exposed	4 / 53 (7.55%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	4	1	0
Respiratory tract infection viral			
subjects affected / exposed	3 / 53 (5.66%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	4	4	0
Folliculitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
Herpes simplex			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Tooth abscess			
subjects affected / exposed	2 / 53 (3.77%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	2	1	1
Tooth infection			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	1 / 51 (1.96%)
occurrences (all)	0	3	1
Urinary tract infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	1	0	2
Viral infection			
subjects affected / exposed	1 / 53 (1.89%)	3 / 51 (5.88%)	0 / 51 (0.00%)
occurrences (all)	1	3	0
Cellulitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1

Fungal skin infection			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	1	1	2
Herpes zoster			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	1	1	1
Acarodermatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Chlamydial infection			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	1 / 51 (1.96%)
occurrences (all)	0	2	1
Ear infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	1	0	3
Gonorrhoea			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Onychomycosis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	3 / 53 (5.66%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	4	0	0
Urethritis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1

Herpes virus infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
Tinea pedis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Amoebic dysentery			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Angular cheilitis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Bacteriuria			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Body tinea			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	1	0
Dermatophytosis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Diverticulitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	1 / 53 (1.89%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	1	2	0

Genital herpes			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Giardiasis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Hepatitis C			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Molluscum contagiosum			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	2 / 51 (3.92%)
occurrences (all)	0	0	2
Otitis externa			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Papilloma viral infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	1	0	1
Shigella infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	2	0
Subcutaneous abscess			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Superinfection bacterial			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0

Acute hepatitis C			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Anal abscess			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	2	0
Anal infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Anorectal infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Endometritis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Enterocolitis viral			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Epididymitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
External ear cellulitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Febrile infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gastritis viral			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Gastroenteritis shigella			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Genital herpes simplex			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Genital infection fungal			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Genitourinary chlamydia infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Gingivitis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Helicobacter infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Impetigo			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Joint abscess			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Lymphogranuloma venereum			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Neurosyphilis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0

Paronychia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Periodontitis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Pilonidal cyst			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Primary syphilis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Proctitis gonococcal			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis acute			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Rash pustular			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Rubella			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Secondary syphilis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Sialoadenitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0

Skin candida			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Tinea cruris			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Tinea infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Toxocariasis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Urethritis gonococcal			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	2	0	0
Vaginal infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Vitamin D deficiency			
subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	2	0	1
Hyperglycaemia			

subjects affected / exposed	2 / 53 (3.77%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	2	0	1
Hyperlipidaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	1 / 51 (1.96%)
occurrences (all)	0	0	2
Decreased appetite			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	1 / 51 (1.96%)
occurrences (all)	0	1	1
Gout			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hypercholesterolaemia			
subjects affected / exposed	0 / 53 (0.00%)	2 / 51 (3.92%)	0 / 51 (0.00%)
occurrences (all)	0	4	0
Hyperinsulinaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Diabetes mellitus			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Fat redistribution			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	1 / 53 (1.89%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 51 (0.00%)	0 / 51 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 53 (0.00%)	1 / 51 (1.96%)	0 / 51 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	EFV 600mg	Open-label DTG 50 mg QD	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	46 / 50 (92.00%)	112 / 138 (81.16%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Melanocytic naevus			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Infected naevus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Papilloma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Prostatic adenoma			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Skin papilloma			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 50 (4.00%)	2 / 138 (1.45%)	
occurrences (all)	2	2	
Aortic arteriosclerosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Arterial fibrosis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Peripheral coldness			

subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Peripheral venous disease			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Phlebitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	4 / 50 (8.00%)	6 / 138 (4.35%)	
occurrences (all)	5	9	
Fatigue			
subjects affected / exposed	6 / 50 (12.00%)	3 / 138 (2.17%)	
occurrences (all)	6	4	
Asthenia			
subjects affected / exposed	0 / 50 (0.00%)	3 / 138 (2.17%)	
occurrences (all)	0	3	
Influenza like illness			
subjects affected / exposed	1 / 50 (2.00%)	3 / 138 (2.17%)	
occurrences (all)	1	3	
Chest pain			
subjects affected / exposed	2 / 50 (4.00%)	2 / 138 (1.45%)	
occurrences (all)	2	2	
Malaise			
subjects affected / exposed	1 / 50 (2.00%)	2 / 138 (1.45%)	
occurrences (all)	1	2	
Oedema peripheral			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Pain			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	1	1	
Adverse drug reaction			

subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Chest discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Drug intolerance			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Feeling drunk			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Feeling hot			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
General physical health deterioration			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Injection site pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Nodule			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Oedema			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Allergy to arthropod sting			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Drug hypersensitivity			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	2	0	

Food allergy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Hypersensitivity			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Multiple allergies			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 50 (2.00%)	3 / 138 (2.17%)	
occurrences (all)	1	3	
Genital lesion			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	1	1	
Ovarian cyst			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	1	1	
Prostatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Breast discomfort			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Breast mass			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Cervical dysplasia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Gynaecomastia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Penile discharge			

subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Peyronie's disease			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 50 (4.00%)	10 / 138 (7.25%)	
occurrences (all)	2	12	
Oropharyngeal pain			
subjects affected / exposed	1 / 50 (2.00%)	5 / 138 (3.62%)	
occurrences (all)	1	5	
Asthma			
subjects affected / exposed	0 / 50 (0.00%)	3 / 138 (2.17%)	
occurrences (all)	0	3	
Sinus congestion			
subjects affected / exposed	2 / 50 (4.00%)	1 / 138 (0.72%)	
occurrences (all)	2	1	
Dyspnoea			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	5	
Rhinitis allergic			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	2	1	
Lung disorder			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	3	
Respiratory disorder			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Asthmatic crisis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Bronchitis chronic		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Bronchopneumopathy		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Dysphonia		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Hyperventilation		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Lower respiratory tract congestion		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Nasal congestion		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Pharyngeal disorder		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Respiratory tract congestion		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Sleep apnoea syndrome		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Snoring		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Upper respiratory tract congestion		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Upper-airway cough syndrome		

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	6 / 50 (12.00%)	5 / 138 (3.62%)	
occurrences (all)	6	5	
Depression			
subjects affected / exposed	5 / 50 (10.00%)	6 / 138 (4.35%)	
occurrences (all)	5	6	
Anxiety			
subjects affected / exposed	3 / 50 (6.00%)	4 / 138 (2.90%)	
occurrences (all)	3	4	
Abnormal dreams			
subjects affected / exposed	3 / 50 (6.00%)	0 / 138 (0.00%)	
occurrences (all)	3	0	
Nightmare			
subjects affected / exposed	4 / 50 (8.00%)	0 / 138 (0.00%)	
occurrences (all)	4	0	
Stress			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Acute stress disorder			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Loss of libido			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Sleep disorder			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Affect lability			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Anxiety disorder			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	

Bulimia nervosa			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Disorientation			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Hallucination			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Libido increased			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Listless			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Mental disorder			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Panic attack			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	2	0	
Post-traumatic stress disorder			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Substance use disorder			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Blood cholesterol increased			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	1	1	
Alanine aminotransferase increased			

subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Blood glucose increased		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Lipase increased		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Amylase increased		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Anal pap smear abnormal		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Bacterial test positive		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Blood creatinine increased		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Cardiac murmur		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Electrocardiogram repolarisation abnormality		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Liver function test increased		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Neutrophil count decreased		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Transaminases increased		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0

Urinary sediment present subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Weight decreased subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Weight increased subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 138 (0.00%) 0	
Injury, poisoning and procedural complications			
Ligament sprain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	3 / 138 (2.17%) 5	
Concussion subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	2 / 138 (1.45%) 2	
Contusion subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Laceration subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Limb injury subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Muscle strain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Procedural pain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Anal injury subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Cervical vertebral fracture			

subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Clavicle fracture		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Epicondylitis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Face injury		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Fall		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Foot fracture		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Joint dislocation		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Rib fracture		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Scrotal haematoma		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Stress fracture		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Tendon rupture		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Vaccination complication		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Wrist fracture		

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Aortic valve incompetence			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Arrhythmia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Bradycardia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Cardiomegaly			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 50 (6.00%)	8 / 138 (5.80%)	
occurrences (all)	5	10	
Dizziness			
subjects affected / exposed	11 / 50 (22.00%)	2 / 138 (1.45%)	
occurrences (all)	13	2	
Paraesthesia			
subjects affected / exposed	2 / 50 (4.00%)	3 / 138 (2.17%)	
occurrences (all)	2	3	
Somnolence			

subjects affected / exposed	2 / 50 (4.00%)	0 / 138 (0.00%)
occurrences (all)	2	0
Dysgeusia		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Memory impairment		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Sciatica		
subjects affected / exposed	1 / 50 (2.00%)	2 / 138 (1.45%)
occurrences (all)	1	3
Hypoaesthesia		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Poor quality sleep		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Restless legs syndrome		
subjects affected / exposed	2 / 50 (4.00%)	0 / 138 (0.00%)
occurrences (all)	2	0
Syncope		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Ageusia		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Anosmia		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Cervical radiculopathy		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Cluster headache		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Cognitive disorder		

subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Hyperaesthesia		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Hypertonia		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Migraine		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Neuropathy peripheral		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Post herpetic neuralgia		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Presyncope		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Sinus headache		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Tongue biting		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Tremor		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Trigeminal neuralgia		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Visual field defect		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Blood and lymphatic system disorders		

Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Neutropenia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Lymphadenitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Ear and labyrinth disorders			
Vertigo subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	0 / 138 (0.00%) 0	
Tinnitus subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	2 / 138 (1.45%) 2	
Ear pain subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 138 (0.00%) 0	
Hypoacusis subjects affected / exposed occurrences (all)	2 / 50 (4.00%) 2	0 / 138 (0.00%) 0	
Cerumen impaction subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 138 (0.00%) 0	
Ear congestion subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Ear pruritus subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Presbycusis			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Eye disorders			
Astigmatism			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Chalazion			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Dark circles under eyes			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Myopia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Visual acuity reduced			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Vitreous floaters			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	5 / 50 (10.00%)	12 / 138 (8.70%)	
occurrences (all)	7	14	
Nausea			
subjects affected / exposed	7 / 50 (14.00%)	2 / 138 (1.45%)	
occurrences (all)	7	2	
Haemorrhoids			
subjects affected / exposed	2 / 50 (4.00%)	8 / 138 (5.80%)	
occurrences (all)	2	10	
Abdominal pain			

subjects affected / exposed	1 / 50 (2.00%)	3 / 138 (2.17%)
occurrences (all)	1	3
Dyspepsia		
subjects affected / exposed	2 / 50 (4.00%)	3 / 138 (2.17%)
occurrences (all)	2	3
Abdominal pain upper		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Gastrooesophageal reflux disease		
subjects affected / exposed	2 / 50 (4.00%)	5 / 138 (3.62%)
occurrences (all)	2	5
Vomiting		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Toothache		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	2
Gastritis		
subjects affected / exposed	1 / 50 (2.00%)	3 / 138 (2.17%)
occurrences (all)	1	3
Abdominal discomfort		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Constipation		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Proctitis		
subjects affected / exposed	0 / 50 (0.00%)	3 / 138 (2.17%)
occurrences (all)	0	4
Faeces soft		
subjects affected / exposed	2 / 50 (4.00%)	0 / 138 (0.00%)
occurrences (all)	2	0
Haematochezia		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Anal fissure		

subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Anal fistula		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Anogenital dysplasia		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Aphthous ulcer		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Epigastric discomfort		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Flatulence		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Inguinal hernia		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Rectal haemorrhage		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Abdominal distension		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Abdominal pain lower		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Anal pruritus		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Anal skin tags		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Anal sphincter hypertonia		

subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Anal ulcer		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Anorectal disorder		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Anorectal ulcer		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Change of bowel habit		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Chronic gastritis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Dental caries		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Enteritis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	3
Enterocolitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Food poisoning		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	2	0
Gastrointestinal disorder		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Hiatus hernia		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Hypoaesthesia oral		

subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Intestinal polyp			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Leukoplakia oral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Odynophagia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Pancreatic atrophy			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Perianal erythema			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Rectal polyp			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Stomatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Tongue discolouration			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Tongue disorder			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Umbilical hernia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	1	1	

Hepatic steatosis			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Cholestasis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	6 / 50 (12.00%)	2 / 138 (1.45%)	
occurrences (all)	6	2	
Pruritus			
subjects affected / exposed	3 / 50 (6.00%)	3 / 138 (2.17%)	
occurrences (all)	3	3	
Dermatitis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	1	1	
Alopecia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Eczema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Night sweats			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Erythema			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Hyperhidrosis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	4	
Photosensitivity reaction			

subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Dry skin		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Hyperkeratosis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Prurigo		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	2
Seborrhoeic dermatitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Skin hyperpigmentation		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Actinic keratosis		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Blister		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Dermal cyst		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Hand dermatitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Intertrigo		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Lipoatrophy		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Miliaria		

subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Palmar erythema		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Pigmentation disorder		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Pruritus generalised		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Psoriasis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Rash macular		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Rash maculo-papular		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Rash papular		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Rash pruritic		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Skin erosion		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Skin lesion		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Solar dermatitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Toxic skin eruption		

subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 50 (0.00%)	3 / 138 (2.17%)	
occurrences (all)	0	4	
Proteinuria			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Nephrolithiasis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Haematuria			
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)	
occurrences (all)	1	1	
Pollakiuria			
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Leukocyturia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Acute kidney injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Chronic kidney disease			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Micturition urgency			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Urethral discharge			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Urethritis noninfective			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	

Urinary hesitation subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Endocrine disorders			
Hypogonadism subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Hypothyroidism subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Goitre subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Musculoskeletal and connective tissue disorders			
Back pain subjects affected / exposed occurrences (all)	4 / 50 (8.00%) 5	10 / 138 (7.25%) 10	
Arthralgia subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	5 / 138 (3.62%) 5	
Musculoskeletal pain subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Myalgia subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	2 / 138 (1.45%) 2	
Muscle spasms subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Exostosis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Pain in extremity subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Tendonitis			

subjects affected / exposed	0 / 50 (0.00%)	4 / 138 (2.90%)
occurrences (all)	0	6
Arthritis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Facet joint syndrome		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Osteopenia		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Plantar fasciitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Ankle impingement		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Chondropathy		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Fistula		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	3	0
Joint stiffness		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Muscle contracture		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Muscle haemorrhage		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Muscular weakness		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Musculoskeletal chest pain		

subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Musculoskeletal discomfort			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Myosclerosis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Neck pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Osteoarthritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Patellofemoral pain syndrome			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Rheumatoid arthritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Synovitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Infections and infestations			
Viral upper respiratory tract infection			
subjects affected / exposed	5 / 50 (10.00%)	20 / 138 (14.49%)	
occurrences (all)	7	27	

Bronchitis		
subjects affected / exposed	5 / 50 (10.00%)	10 / 138 (7.25%)
occurrences (all)	6	14
Influenza		
subjects affected / exposed	3 / 50 (6.00%)	6 / 138 (4.35%)
occurrences (all)	3	9
Syphilis		
subjects affected / exposed	4 / 50 (8.00%)	12 / 138 (8.70%)
occurrences (all)	4	15
Respiratory tract infection		
subjects affected / exposed	3 / 50 (6.00%)	9 / 138 (6.52%)
occurrences (all)	4	13
Upper respiratory tract infection		
subjects affected / exposed	1 / 50 (2.00%)	7 / 138 (5.07%)
occurrences (all)	1	10
Sinusitis		
subjects affected / exposed	4 / 50 (8.00%)	6 / 138 (4.35%)
occurrences (all)	6	6
Pharyngitis		
subjects affected / exposed	2 / 50 (4.00%)	3 / 138 (2.17%)
occurrences (all)	2	3
Gastroenteritis		
subjects affected / exposed	1 / 50 (2.00%)	5 / 138 (3.62%)
occurrences (all)	1	5
Rhinitis		
subjects affected / exposed	0 / 50 (0.00%)	5 / 138 (3.62%)
occurrences (all)	0	7
Tonsillitis		
subjects affected / exposed	1 / 50 (2.00%)	3 / 138 (2.17%)
occurrences (all)	2	5
Oral herpes		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Respiratory tract infection viral		
subjects affected / exposed	1 / 50 (2.00%)	2 / 138 (1.45%)
occurrences (all)	1	2

Folliculitis		
subjects affected / exposed	0 / 50 (0.00%)	4 / 138 (2.90%)
occurrences (all)	0	4
Herpes simplex		
subjects affected / exposed	1 / 50 (2.00%)	3 / 138 (2.17%)
occurrences (all)	1	3
Tooth abscess		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Tooth infection		
subjects affected / exposed	0 / 50 (0.00%)	3 / 138 (2.17%)
occurrences (all)	0	3
Urinary tract infection		
subjects affected / exposed	0 / 50 (0.00%)	3 / 138 (2.17%)
occurrences (all)	0	3
Viral infection		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	3
Cellulitis		
subjects affected / exposed	2 / 50 (4.00%)	1 / 138 (0.72%)
occurrences (all)	2	1
Fungal skin infection		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Herpes zoster		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Acarodermatitis		
subjects affected / exposed	0 / 50 (0.00%)	3 / 138 (2.17%)
occurrences (all)	0	5
Chlamydial infection		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Conjunctivitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1

Ear infection		
subjects affected / exposed	1 / 50 (2.00%)	2 / 138 (1.45%)
occurrences (all)	1	2
Furuncle		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Gonorrhoea		
subjects affected / exposed	1 / 50 (2.00%)	2 / 138 (1.45%)
occurrences (all)	1	2
Onychomycosis		
subjects affected / exposed	1 / 50 (2.00%)	2 / 138 (1.45%)
occurrences (all)	1	2
Otitis media		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Urethritis		
subjects affected / exposed	1 / 50 (2.00%)	2 / 138 (1.45%)
occurrences (all)	1	2
Gastroenteritis viral		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Herpes virus infection		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Nasopharyngitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	2
Pharyngitis streptococcal		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Tinea pedis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Amoebic dysentery		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0

Angular cheilitis		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Bacteriuria		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Body tinea		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Cystitis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Dermatophytosis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Diverticulitis		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	3
Fungal infection		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Genital herpes		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Giardiasis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Hepatitis C		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Laryngitis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Molluscum contagiosum		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0

Otitis externa		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Papilloma viral infection		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Shigella infection		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Staphylococcal infection		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	3	0
Subcutaneous abscess		
subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)
occurrences (all)	0	2
Superinfection bacterial		
subjects affected / exposed	1 / 50 (2.00%)	1 / 138 (0.72%)
occurrences (all)	1	1
Vulvovaginal mycotic infection		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	2	0
Acute hepatitis C		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Acute sinusitis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Anal abscess		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Anal infection		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Anorectal infection		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1

Candida infection		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Endometritis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Enterocolitis viral		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Epididymitis		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
External ear cellulitis		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Febrile infection		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Gastritis viral		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Gastroenteritis shigella		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Genital herpes simplex		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Genital infection fungal		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Genitourinary chlamydia infection		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Gingivitis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0

Helicobacter infection		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Impetigo		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Infection		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Joint abscess		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Lower respiratory tract infection		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Lymphogranuloma venereum		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Neurosyphilis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Paronychia		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Periodontitis		
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)
occurrences (all)	0	0
Pilonidal cyst		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1
Pneumonia		
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)
occurrences (all)	1	0
Primary syphilis		
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)
occurrences (all)	0	1

Proctitis gonococcal subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 138 (0.00%) 0
Pulpitis dental subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	0 / 138 (0.00%) 0
Pyelonephritis acute subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1
Rash pustular subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0
Rubella subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1
Secondary syphilis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1
Sialoadenitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1
Skin candida subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0
Staphylococcal skin infection subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1
Tinea cruris subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0
Tinea infection subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0
Toxocariasis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0

Urethritis gonococcal subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Urinary tract infection bacterial subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Vaginal infection subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	1 / 138 (0.72%) 1	
Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Metabolism and nutrition disorders			
Vitamin D deficiency subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	4 / 138 (2.90%) 4	
Hyperglycaemia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	3 / 138 (2.17%) 3	
Hyperlipidaemia subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	1 / 138 (0.72%) 1	
Decreased appetite subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Gout subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	2 / 138 (1.45%) 2	
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 138 (0.00%) 0	
Hyperinsulinaemia			

subjects affected / exposed	0 / 50 (0.00%)	2 / 138 (1.45%)	
occurrences (all)	0	2	
Diabetes mellitus			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Fat redistribution			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Fluid retention			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 138 (0.72%)	
occurrences (all)	0	1	
Hyponatraemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 138 (0.00%)	
occurrences (all)	1	0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 138 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 March 2009	<ul style="list-style-type: none">• Incorporation of text to comply with GlaxoSmithKline Policy 408• Deletion of previous Section 6.4.6.2 and reformatting of entry criteria to comply with new standards.
18 June 2009	<ul style="list-style-type: none">• Removal of exclusion of women of childbearing potential following availability of final embryo-fetal toxicology data• Inclusion of additional toxicology data and exclusion criteria and toxicity management guidelines• Correction of minor typographical errors and stylistic changes.
14 August 2009	<ul style="list-style-type: none">• Change minimum entry cluster of differentiation 4 (CD4) plus cell criterion to greater than and equal to 200 cells/cubic millimeter (mm³)
31 August 2009	<ul style="list-style-type: none">• Correction of omissions in Amendment No. 03• Allow real-time urine pregnancy testing at Day 1.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported