Clinical trial results:
A MULTI-CENTER, OPEN LABEL, EXPANDED ACCESS TRIAL OF MARAVIROC

Summary

EudraCT number	2006-004306-50
Trial protocol	IE GB BE CZ DE PT ES NL AT GR IT DK
Global end of trial date	30 June 2010

Results information

Result version number	v1 (current)
This version publication date	13 April 2016
First version publication date	29 July 2015

Trial information

Trial identification

Sponsor protocol code	A4001050

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00426660
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 East 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 November 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 June 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the maraviroc expanded access program is to facilitate access to maraviroc for subjects, who have limited therapeutic options and to collect safety data in a larger and more diverse patient population than that which participated in the phase 2/3 clinical trials.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed, in particular, those affording greater protection to the safety of study subjects.

Background therapy:

Maraviroc dosage was adjusted according to optimized background therapy (OBT). OBT was selected by the investigator on the basis of local treatment guidelines, treatment history, resistance test results (if available), safety considerations and his/her clinical judgment. OBT was open-label and not provided by the sponsor. Investigational antiretroviral agents available through pre-approval expanded access programs conducted by other pharmaceutical industries sponsors or in Phase 3 or 4 clinical trials or by other means may be appropriate for use as part of background therapy. Subjects experiencing toxicity attributed to drugs in the background regimen were allowed to substitute another antiretroviral agent during the trial. All concomitant antiretroviral agents were recorded on the appropriate CRF.

Evidence for comparator: -

Actual start date of recruitment	21 July 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Portugal: 8
Country: Number of subjects enrolled	Spain: 132
Country: Number of subjects enrolled	United Kingdom: 18
Country: Number of subjects enrolled	Austria: 4
Country: Number of subjects enrolled	Belgium: 38
Country: Number of subjects enrolled	France: 193
Country: Number of subjects enrolled	Greece: 11
Country: Number of subjects enrolled	Ireland: 2
Country: Number of subjects enrolled	Italy: 154
Country: Number of subjects enrolled	Australia: 30
Country: Number of subjects enrolled	Canada: 13
Country: Number of subjects enrolled	Chile: 4

Country: Number of subjects enrolled	Argentina: 15
Country: Number of subjects enrolled	Hong Kong: 1
Country: Number of subjects enrolled	India: 28
Country: Number of subjects enrolled	Malaysia: 14
Country: Number of subjects enrolled	Mexico: 22
Country: Number of subjects enrolled	Puerto Rico: 5
Country: Number of subjects enrolled	Romania: 22
Country: Number of subjects enrolled	Switzerland: 5
Country: Number of subjects enrolled	Taiwan: 1
Country: Number of subjects enrolled	United States: 293
Country: Number of subjects enrolled	Costa Rica: 13
Worldwide total number of subjects	1032
EEA total number of subjects	588

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)	1
Adults (18-64 years)	1008
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Of 2584 subjects screened, 1047 subjects were enrolled in the study. Of these 1047 subjects, 1032 subjects were treated with maraviroc.

Period 1

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

Arms

Arm title	Maraviroc

Arm description:

Maraviroc 150 milligrams (mg) twice daily (BID), 600 mg BID, or 300 mg BID; dose administered depending on concomitant medications in combination with optimized background therapy (OBT) according to local standard of care.

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

Dosage and administration details:

Maraviroc 150 mg twice daily (BID), 600 mg BID, or 300 mg BID; administered orally.

Number of subjects in period 1	Maraviroc
Started	1032
treated	1032
Safety Analysis Set	1032
Completed	916
Not completed	116
Consent withdrawn by subject	18
Adverse Event	23
Death	14
Insufficient Clinical Response	22
Unspecified	23
Protocol Violation	1
Lost to follow-up	15

Baseline characteristics

Reporting groups	
Reporting group title	Maraviroc
Reporting group description:	
Maraviroc 150 milligrams (mg) twice daily (BID), 600 mg BID, or 300 mg BID; dose administered depending on concomitant medications in combination with optimized background therapy (OBT) according to local standard of care.	

Reporting group values	Maraviroc	Total	
Number of subjects	1032	1032	
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 45.6 ± 8.6	 -	
Gender categorical Units: Subjects			
Female Male	205 827	205 827	
Baseline Overall Viral Load: Absolute Value			
Human Immunodeficiency Virus (HIV-1) Ribonucleic Acid (RNA) at baseline (original scale). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistics at baseline for overall viral load was 979. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: copies/millilitre (mL) arithmetic mean standard deviation	 117846.1 ± 321426.5	 -	
Baseline Viral Load less than (<) 100,000: Absolute Value			
HIV-1 RNA at baseline (original scale). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistics at baseline for viral load < 100,000 was 729. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: copies/mL arithmetic mean standard deviation	 22395.9 ± 25974.4	 -	
Baseline Viral Load Gtearter Than or Equal to (>=) 100,000: Absolute Value			
HIV-1 RNA at baseline (original scale). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistics at baseline for viral load >= 100,000 was 250. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: copies/mL arithmetic mean standard deviation	 396179 ± 547142.6	 -	
Baseline Overall Viral Load: Absolute Value			
HIV-1 RNA at baseline (original scale). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to			

summary statistics at baseline for overall viral load was 979. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: copies/mL median full range (min-max)	 25109.5 39 to 5728492	 -	
Baseline Viral Load <100,000: Absolute Value			
HIV-1 RNA at baseline (original scale). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistics at baseline for viral load < 100,000 was 729. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: copies/mL median full range (min-max)	 11028.5 39 to 99643	 -	
Baseline Viral Load >=100,000: Absolute Value			
HIV-1 RNA at baseline (original scale). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistics at baseline for viral load >= 100,000 was 250. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: copies/mL median full range (min-max)	 234750 100000 to 5728492	 -	
Baseline Overall Viral Load: Log Scale			
HIV-1 RNA at baseline (log10 copies/mL). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistic at Baseline was 979. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: log10 copies/mL arithmetic mean standard deviation	 4.259 ± 1.0182	 -	
Baseline Viral Load <100,000: Log Scale			
HIV-1 RNA at baseline (log10 copies/mL). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistic at Baseline was 729. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: log10 copies/mL arithmetic mean standard deviation	 3.859 ± 0.8517	 -	
Baseline Viral Load >=100,000: Log Scale			
HIV-1 RNA at baseline (log10 copies/mL). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistic at Baseline was 250. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: log10 copies/mL arithmetic mean standard deviation	 5.423 ± 0.3496	 -	
Baseline Overall Viral Load: Log Scale			
HIV-1 RNA at baseline (log10 copies/mL). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number ofsubjects contributing to summary statistic at Baseline was 979. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: log10 copies/mL median full range (min-max)	 4.4 1.591 to 6.758	 -	
Baseline Viral Load <100,000: Log Scale			
HIV-1 RNA at baseline (log10 copies/mL). Baseline value calculated as average of screening and			

baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistic at Baseline was 729. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: log10 copies/mL			
median	4.043		
full range (min-max)	1.591 to 4.998	-	
Baseline Viral Load >=100,000: Log Scale			
HIV-1 RNA at baseline (log10 copies/mL). Baseline value calculated as average of screening and baseline values if both values were within 1 log10 difference. Number of subjects contributing to summary statistic at Baseline was 250. Viral loads were not available uniformly for all subjects enrolled in study.			
Units: log10 copies/mL			
median	5.371		
full range (min-max)	5 to 6.758	-	

End points

End points reporting groups

Reporting group title	Maraviroc

Reporting group description:

Maraviroc 150 milligrams (mg) twice daily (BID), 600 mg BID, or 300 mg BID; dose administered depending on concomitant medications in combination with optimized background therapy (OBT) according to local standard of care.

Primary: Percentage of Subjects With Grade 3 and Grade 4 Adverse Events (AE)

End point title	Percentage of Subjects With Grade 3 and Grade 4 Adverse Events (AE)[1]

End point description:

AEs as defined by the Division of AIDS (DAIDS) toxicity grading scale: Grade 3 = severe: interrupted usual daily activity and traditionally required systemic drug therapy or other treatment. Grade 4 = very severe: events that were unacceptable and intolerable or were irreversable or caused imminent danger of death. If same subject had more than 1 occurrence in the same preferred term event category, only the most severe (grade 4) occurrence was taken. Treatment-related = investigator assessment of a reasonable possibility that the investigational product caused or contributed to the AE. Safety analysis set: all subjects who were randomized and received at least one dose of study medication.

End point type	Primary

End point timeframe:

Baseline up to Week 144

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: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
Grade 3 AE: all causality	13.2			
Grade 3 AE: treatment related	2.4			
Grade 4 AE: all causality	6.3			
Grade 4 AE: treatment related	1.6			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Grade 3 Laboratory Abnormalities Without Regards to Baseline Abnormalities

End point title	Percentage of Subjects With Grade 3 Laboratory Abnormalities Without Regards to Baseline Abnormalities[2]

End point description:

Laboratory abnormalities as defined by the Division of AIDS (DAIDS) toxicity grading scale: Grade 3, Severe =events that interrupted subjects usual daily activity and traditionally required systemic drug

therapy or other treatment. Safety analysis set. N = number of subjects evaluable for laboratory abnormalities (with at least one observation of a laboratory test while on study treatment or during lag time); n = number of subjects with at least one observation of given laboratory test while on study treatment or during lag time.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1014			
Units: percentage of subjects				
number (not applicable)				
Alanine aminotransferase (ALT) (n=1013)	2.17			
Aspartate aminotransferase (AST) (n=1013)	2.07			
Absolute Neutrophil Count (n=1004)	0.7			
Alkaline Phosphatase (n=1014)	0.39			
Creatinine (n=1014)	0.49			
Gamma-glutamyl transpeptidase (GGT) (n=1014)	4.73			
Hemoglobin (n=1005)	0.2			
Hyperbilirubinemia (n=1013)	1.28			
Hyperuricemia (n=1014)	0.69			
Hypophosphatemia (n=1014)	0.2			
Lipase (n=409)	4.4			
Platelets (n=997)	1.5			
Potassium (hyperkalemia) (n=1014)	0.1			
Serum Amylase (n=1014)	4.83			
Sodium (hypernatremia) (n=1014)	0.1			
Triglycerides (n=1014)	4.73			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Grade 4 Laboratory Abnormalities Without Regards to Baseline Abnormalities

End point title	Percentage of Subjects With Grade 4 Laboratory Abnormalities Without Regards to Baseline Abnormalities[3]

End point description:

Laboratory abnormalities as defined by the Division of AIDS (DAIDS) toxicity grading scale: Grade 4, Very Severe = events which were unacceptable and intolerable or were irreversible or caused the subjects to be in imminent danger of death. Safety analysis set. N = number of subjects evaluable for laboratory abnormalities (with at least one observation of a laboratory test while on study treatment or during lag time); n = number of subjects with at least one observation of given laboratory test while on study treatment or during lag time.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1014			
Units: percentage of subjects				
number (not applicable)				
ALT (n=1013)	0.79			
AST (n=1013)	0.39			
Absolute Neutrophil Count (n=1004)	0.2			
Alkaline Phosphatase (n=1014)	0			
Creatinine (n=1014)	0.1			
GGT (n=1014)	1.48			
Hemoglobin (n=1005)	0.1			
Hyperbilirubinemia (n=1013)	0.3			
Hyperuricemia (n=1014)	0.1			
Hypophosphatemia (n=1014)	0			
Lipase (n=409)	1.22			
Platelets (n=997)	0.3			
Potassium (hyperkalemia) (n=1014)	0.2			
Serum Amylase (n=1014)	0.3			
Sodium (hypernatremia) (n=1014)	0.2			
Triglycerides (n=1014)	1.97			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Acquired Immunodeficiency Syndrome (AIDS)-Defining Illnesses

End point title	Percentage of Subjects With Acquired Immunodeficiency Syndrome (AIDS)-Defining Illnesses[4]

End point description:

Treatment-emergent AIDS-defining opportunistic illnesses based on investigator classification guided by a predefined list of clinical Category C adverse events per Center for Disease Control (CDC) HIV Classification System. Includes events occurring up to 30 days after last dose of study drug. Safety analysis set.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
AIDS encephalopathy	0.1			
Bone tuberculosis	0.1			
Cytomegalovirus infection	0.2			
Extrapulmonary tuberculosis	0.1			
Meningitis cryptococcal	0.1			
Meningitis tuberculous	0.1			
Mycobacterium avium complex infection	0.1			
Mycobacterium kansasii infection	0.1			
Oesophageal candidiasis	0.6			
Pancreatitis bacterial	0.1			
Pneumocystis jiroveci pneumonia	0.1			
Progressive multifocal leukoencephalopathy	0.1			
Pulmonary tuberculosis	0.5			
Toxoplasmosis	0.1			
B-cell lymphoma	0.1			
Hodgkin’s disease	0.1			
Kaposi’s sarcoma	0.2			
Encephalopathy	0.1			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Possible Acquired Immunodeficiency Syndrome (AIDS) Related Infections and Malignancies by Baseline Viral Load

End point title	Percentage of Subjects With Possible Acquired Immunodeficiency Syndrome (AIDS) Related Infections and Malignancies by Baseline Viral Load[5]

End point description:

Due to the limited data available for this endpoint, a summary of AIDS related infections by baseline viral load is not clinically meaningful.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	0[6]			
Units: percentage of subjects				
number (not applicable)				

Notes:

[6] - Data not analyzed due to the limited data available for this endpoint.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Possible Acquired Immunodeficiency Syndrome (AIDS) Related Infections and Malignancies by Baseline/Nadir CD4 Cell Counts

End point title	Percentage of Subjects With Possible Acquired Immunodeficiency Syndrome (AIDS) Related Infections and Malignancies by Baseline/Nadir CD4 Cell Counts[7]

End point description:

Due to the limited data available for this endpoint, a summary of AIDS related infections by by Baseline/Nadir CD4 Cell Counts is not clinically meaningful.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[7] - 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: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	0[8]			
Units: percentage of subjects				
number (not applicable)				

Notes:

[8] - Data not analyzed due to the limited data available for this endpoint.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Possible Acquired Immunodeficiency Syndrome (AIDS) Related Infections and Malignancies by Time on Therapy

End point title	Percentage of Subjects With Possible Acquired Immunodeficiency Syndrome (AIDS) Related Infections and Malignancies by Time on Therapy[9]

End point description:

Due to the limited data available for this endpoint, a summary of AIDS related infections by time is not clinically meaningful.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[9] - 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: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	0[10]			
Units: percentage of subjects				
number (not applicable)				

Notes:

[10] - Data not analyzed due to the limited data available for this endpoint.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With All Causality Treatment-emergent Adverse (AEs) Events by Gender

End point title	Percentage of Subjects With All Causality Treatment-emergent Adverse (AEs) Events by Gender[11]

End point description:

Treatment-emergent AEs by gender that occurred up to 30 days after the last dose of study medication. Safety analysis set; n = number of subjects evaluable for adverse events.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[11] - 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: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
Male (n=827)	69.6			
Female (n=205)	73.7			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Treatment-emergent Adverse Events (AEs) by Race

End point title	Percentage of Subjects With Treatment-emergent Adverse Events (AEs) by Race[12]

End point description:

Treatment-emergent AEs by race that occurred up to 30 days after the last dose of study medication. Safety analysis set; n = number of subjects evaluable for adverse events.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[12] - 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: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
White (n=817)	68.5			
Black (n=106)	67.9			
Asian (n=54)	88.9			
Other Unspecified (n=55)	85.5			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Treatment-emergent Adverse Events (AEs) by Age

End point title	Percentage of Subjects With Treatment-emergent Adverse Events (AEs) by Age[13]

End point description:

Treatment-emergent AEs by age that occurred up to 30 days after the last dose of study medication. Safety analysis set; n = number of subjects evaluable for adverse events.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[13] - 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: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
<18 years (n=1)	100			
18 to 44 years (n=515)	71.7			
45 to 64 years (n=493)	68.6			
>=65 years (n=23)	82.6			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Treatment-emergent Averse Events (AEs) by Baseline Hepatitis B and Hepatitis C Virus Serology Status

End point title	Percentage of Subjects With Treatment-emergent Averse Events (AEs) by Baseline Hepatitis B and Hepatitis C Virus Serology Status[14]

End point description:

Treatment emergent AEs by hepatis B and hepatitis C serology status that occurred up to 30 days post last dose. Safety analysis set; n = number of subjects evaluable for adverse events. Abbreviations: HBV = hepatitis B virus, HBC = hepatitis C virus.

End point type	Primary

End point timeframe:

Baseline up to Week 144

Notes:

[14] - 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: As this was an open label, non-randomized, single arm study, only descriptive data was planned to be reported.

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
HBV: negative (n=897)	71.3			
HBV: positive (n=60)	65			
HBV: missing: (n=75)	64			
HCV: negative (n=794)	72.7			
HCV: positive (n=158)	62.7			
HCV: missing (n=80)	63.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With ≥0.5 log10 Reduction From Baseline in Human Immunodeficiency Virus 1 Ribonucleic Acid (HIV 1 RNA)

End point title	Percentage of Subjects With ≥0.5 log10 Reduction From Baseline in Human Immunodeficiency Virus 1 Ribonucleic Acid (HIV 1 RNA)

End point description:

Defined as HIV-1 RNA levels < 400 Copies/mL or at least 0.5 Log 10-decrease from baseline in HIV-1

RNA levels. Baseline value calculated as average of the screening and baseline values if both values were within 1 log10 difference. Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
Day 2-7 (n=26)	46.2			
Week 2 (n=226)	93.8			
Week 4 (n=773)	93			
Week 8 (n=761)	93.2			
Week 12 (n=756)	94			
Week 16 (n=155)	87.7			
Week 20 (n=131)	93.1			
Week 24 (n=557)	91.9			
Week 32 (n=202)	93.1			
Week 40 (n=227)	91.2			
Week 48 (n=228)	89			
Week 60 (n=160)	90			
Week 72 (n=125)	88			
Week 84 (n=79)	84.8			
Week 96 (n=48)	91.7			
Week 108 (n=18)	100			
Week 120 (n=9)	100			
Week 132 (n=4)	100			
Week 144 (n=1)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With ≥1.0 log10 Reduction From Baseline in HIV 1 RNA

End point title	Percentage of Subjects With ≥1.0 log10 Reduction From Baseline in HIV 1 RNA

End point description:

Defined as HIV-1 RNA levels < 400 copies/mL or at least 1.0 Log 10-decrease from baseline in HIV-1 RNA levels. Baseline value calculated as average of the screening and baseline values if both values were within 1 log10 difference. Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
Day 2-7 (n=26)	30.8			
Week 2 (n=226)	90.3			
Week 4 (n=773)	90.2			
Week 8 (n=761)	91.2			
Week 12 (n=756)	91.3			
Week 16 (n=155)	82.6			
Week 20 (n=131)	89.3			
Week 24 (n=557)	89			
Week 32 (n=202)	90.1			
Week 40 (n=227)	87.7			
Week 48 (n=228)	86.4			
Week 60 (n=160)	85.6			
Week 72 (n=125)	83.2			
Week 84 (n=79)	79.7			
Week 96 (n=48)	85.4			
Week 108 (n=18)	100			
Week 120 (n=9)	100			
Week 132 (n=4)	100			
Week 144 (n=1)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With HIV-1 RNA Levels Below the Limit of Quantification: <400 Copies/mL

End point title	Percentage of Subjects With HIV-1 RNA Levels Below the Limit of Quantification: <400 Copies/mL

End point description:

Limit of quantification defined as <400 copies/mL. Baseline value calculated as average of the screening and baseline values if both values were within 1 log 10 difference. Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
Baseline (n=979)	6.7			
Day 2-7 (n=26)	3.8			
Week 2 (n=226)	58.8			
Week 4 (n=773)	72.7			
Week 8 (n=761)	78.8			
Week 12 (n=756)	82.5			
Week 16 (n=155)	75.5			
Week 20 (n=131)	83.2			
Week 24 (n=557)	84.4			
Week 32 (n=202)	83.7			
Week 40 (n=227)	81.1			
Week 48 (n=228)	80.7			
Week 60 (n=160)	78.1			
Week 72 (n=125)	72.8			
Week 84 (n=79)	74.7			
Week 96 (n=48)	75			
Week 108 (n=18)	88.9			
Week 120 (n=9)	77.8			
Week 132 (n=4)	100			
Week 144 (n=1)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With HIV-1 RNA Levels Below the Limit of Quantification: <50 Copies/mL

End point title	Percentage of Subjects With HIV-1 RNA Levels Below the Limit of Quantification: <50 Copies/mL

End point description:

Limit of quantification defined as <50 copies/mL. Baseline value calculated as average of the screening and baseline values if both values were within 1 log 10 difference. Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of subjects				
number (not applicable)				
Baseline (n=979)	1.7			
Day 2-7 (n=26)	0			
Week 2 (n=226)	19.9			
Week 4 (n=773)	30.1			
Week 8 (n=761)	43.1			
Week 12 (n=756)	45.8			
Week 16 (n=155)	37.4			
Week 20 (n=131)	42.7			
Week 24 (n=557)	55.8			
Week 32 (n=202)	57.4			
Week 40 (n=227)	54.6			
Week 48 (n=228)	54.8			
Week 60 (n=160)	51.9			
Week 72 (n=125)	49.6			
Week 84 (n=79)	55.7			
Week 96 (n=48)	54.2			
Week 108 (n=18)	77.8			
Week 120 (n=9)	44.4			
Week 132 (n=4)	75			
Week 144 (n=1)	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CD4 Cell Count

End point title	Change From Baseline in CD4 Cell Count

End point description:

Change from baseline in cluster of differentiation 4 helper T cells (CD4) cell count. If baseline value was not available, it was taken from immediate preceding non-missing value. Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: cells per microliter (cells/mcL)				
arithmetic mean (standard deviation)				
Day 2-7 (n=6)	28.5 (± 76.18)			

Week 2 (n=213)	49.7 (± 93.15)			
Week 4 (n=762)	68.9 (± 124.31)			
Week 8 (n=739)	94.5 (± 122.94)			
Week 12 (n=738)	95.7 (± 124.42)			
Week 16 (n=149)	85.9 (± 124.37)			
Week 20 (n=130)	106.6 (± 112.26)			
Week 24 (n=552)	127.8 (± 139.42)			
Week 32 (n=197)	124.1 (± 150.44)			
Week 40 (n=232)	129.2 (± 144.31)			
Week 48 (n=222)	140.5 (± 154.46)			
Week 60 (n=161)	134 (± 151.52)			
Week 72 (n=124)	147 (± 160.92)			
Week 84 (n=72)	141.1 (± 147.55)			
Week 96 (n=50)	160.3 (± 160.78)			
Week 108 (n=19)	242.9 (± 167.06)			
Week 120 (n=8)	117.9 (± 203.49)			
Week 132 (n=4)	179 (± 109.94)			
Week 144 (n=1)	93 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CD4 Cell Count Percent

End point title	Change From Baseline in CD4 Cell Count Percent

End point description:

Change from baseline in CD4 cell count percent . If baseline value was not available, it was taken from immediate preceding non-missing value.
Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of lymphocytes				
arithmetic mean (standard deviation)				
Days 2-7 (n=6)	-1.3 (± 1.56)			
Week 2 (n=206)	1.8 (± 3.79)			
Week 4 (n=733)	1.6 (± 4.84)			
Week 8 (n=722)	1.4 (± 6.12)			
Week 12 (n=708)	1.6 (± 5.45)			
Week 16 (n=141)	1.9 (± 4.63)			
Week 20 (n=125)	2.2 (± 6.17)			
Week 24 (n=531)	2.8 (± 4.55)			
Week 32 (n=191)	3.2 (± 5.38)			
Week 40 (n=218)	3.7 (± 4.97)			
Week 48 (n=210)	3.5 (± 5.87)			
Week 60 (n=148)	4.5 (± 6.1)			
Week 72 (n=116)	5 (± 6.33)			
Week 84 (n=64)	5.7 (± 6.73)			
Week 96 (n=41)	3.9 (± 6.36)			
Week 108 (n=19)	6.3 (± 6.86)			
Week 120 (n=7)	5.7 (± 9.07)			
Week 132 (n=4)	8.5 (± 8.35)			
Week 144 (n=1)	1 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CD8 Cell Count

End point title	Change From Baseline in CD8 Cell Count

End point description:

Change from baseline in cluster of differentiation 8 suppressor T cells (CD8) cell count. If baseline value was not available, it was taken from immediate preceding non-missing value. Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: cells/mcL				
arithmetic mean (standard deviation)				
Day 2-7 (n=6)	268.5 (± 262.5)			

Week 2 (n=201)	78.2 (± 343.85)			
Week 4 (n=701)	205.6 (± 509.7)			
Week 8 (n=692)	345.6 (± 599.98)			
Week 12 (n=696)	309.4 (± 578.91)			
Week 16 (n=129)	259.6 (± 430.78)			
Week 20 (n=119)	325.2 (± 621.46)			
Week 24 (n=523)	251.3 (± 498.85)			
Week 32 (n=185)	185.2 (± 484.74)			
Week 40 (n=222)	160.9 (± 471.99)			
Week 48 (n=214)	153.2 (± 464.73)			
Week 60 (n=157)	76.9 (± 467.64)			
Week 72 (n=120)	68.7 (± 502.73)			
Week 84 (n=70)	-11.6 (± 548.85)			
Week 96 (n=45)	56.6 (± 403.1)			
Week 108 (n=19)	147.5 (± 600.55)			
Week 120 (n=8)	-135.1 (± 517.02)			
Week 132 (n=4)	-363.3 (± 882.3)			
Week 144 (n=1)	642 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in CD8 Cell Count Percent

End point title	Change From Baseline in CD8 Cell Count Percent

End point description:

Change from baseline in CD8 cell count percent . If baseline value was not available, it was taken from immediate preceding non-missing value. Safety analysis set; n = number of subjects contributing to summary statistic at given timepoint.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	1032			
Units: percentage of lymphocytes				
arithmetic mean (standard deviation)				
Day 2-7 (n=6)	3 (± 3.42)			
Week 2 (n=197)	-1.5 (± 7.68)			
Week 4 (n=689)	-0.3 (± 8.08)			
Week 8 (n=683)	0.4 (± 9.62)			
Week 12 (n=675)	-0.9 (± 9.95)			
Week 16 (n=125)	0.7 (± 8.66)			
Week 20 (n=115)	-0.7 (± 10.08)			
Week 24 (n=510)	-3.2 (± 8.92)			
Week 32 (n=184)	-4 (± 9.09)			
Week 40 (n=215)	-4.5 (± 8.9)			
Week 48 (n=202)	-5.1 (± 10.63)			
Week 60 (n=146)	-5 (± 11.9)			
Week 72 (n=113)	-6.2 (± 9.87)			
Week 84 (n=64)	-8.2 (± 15.52)			
Week 96 (n=40)	-9.5 (± 10.18)			
Week 108 (n=19)	-14.5 (± 9.99)			
Week 120 (n=6)	-14.5 (± 13.41)			
Week 132 (n=4)	-16.8 (± 12.89)			
Week 144 (n=1)	-2 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Median Time to Virologic Failure

End point title	Median Time to Virologic Failure

End point description:

Computed as time from the first dose of study medication to the loss of virologic response. Virologic failure defined as: failure to achieve a reduction from baseline (BL) in HIV 1 RNA ≥ 0.5 log10 copies /mL by the second viral load determination (unless viral load was below the lower limit level of quantification [LLOQ]); or a ≥ 0.5 log10 increase from nadir in HIV 1 RNA after achieving a HIV 1 RNA reduction from BL >0.5 log10 copies/mL; or a HIV 1 RNA level of >1000 copies/mL after having achieved a HIV 1 RNA level below LLOQ. Safety analysis set. For the calculation of the time to virologic failure, any visits with no data were excluded. Subjects who were not virologic failures were censored at the last available observation.

End point type	Secondary

End point timeframe:

Day 1 up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	192[15]			
Units: days				
median (inter-quartile range (Q1-Q3))	86.5 (58 to 169)			

Notes:

[15] - N = number of subjects with virologic failure.

Attachments (see zip file)	Stat Analysis Median Time to Virologic Failure/Statistical

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Changes in HIV-1 RNA Level in Subjects Meeting the Definition of Virologic Failure

End point title	Percentage of Subjects With Changes in HIV-1 RNA Level in Subjects Meeting the Definition of Virologic Failure

End point description:

Reasons for virologic failure: A) failure to achieve a reduction in HIV-1 RNA>=0.5 log10 copies/ml from baseline (BL) by second viral load determination (unless below level of quantification [LOQ]); B) >=0.5 log10 increase from nadir in HIV-1 RNA after achieving an HIV-1 RNA reduction from BL >0.5 log10 copies/ml ; C) HIV-1 RNA >1000 copies/ml after having achieved an HIV-1 RNA below LOQ. Safety analysis set.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	192[16]			
Units: percentage of subjects				
number (not applicable)				
Reduction in HIV-1 RNA<0.5 log10 copies/ml	43.75			
>=0.5 log10 increase from nadir in HIV-1 RNA	31.77			
HIV-1 RNA >1000 copies/ml	18.75			
Reduction <0.5 log10 + HIV-1 RNA >1000 copies/ml	3.13			
>=0.5 log10 increase from nadir + HIV-1 RNA >1000	2.6			

Notes:

[16] - N = number of subjects with virologic failure.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Change in Chemokine Co-receptor Tropism From Screening to Time of Virologic Failure

End point title	Percentage of Subjects With Change in Chemokine Co-receptor Tropism From Screening to Time of Virologic Failure

End point description:

Tropism status (CCR5 [R5], Dual Mixed [DM], or Non-reportable [NR]) at Screening [Scr] and R5, CXCR4 [X4], DM, or NR) at time of virologic failure (V fail). Virologic failure defined as: failure to achieve a reduction from baseline (BL) in HIV 1 RNA ≥0.5 log10 copies/mL by second viral load determination (unless viral load was below lower limit level of quantification [LLOQ]); or a ≥ 0.5 log10 increase from nadir in HIV 1 RNA after achieving HIV 1 RNA reduction from BL >0.5 log10 copies/mL; or a HIV 1 RNA level of >1000 copies/mL after having achieved a HIV 1 RNA level below LLOQ. Safety analysis set. Abbreviations: Scr = screening, R5 = CCR5 tropic HIV-1, X4=CXCR4 tropic HIV-1, DM = dual mixed, NR = non-reportable, Missing = subjects with VF who did not have tropism result within specified screening period (Scr missing: -42 days to Day 0) or at the time of VF. 1 subject with NR was erroneously enrolled in the study.

End point type	Secondary

End point timeframe:

Screening up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	192[17]			
Units: percentage of subjects				
number (not applicable)				
Scr: Missing; V fail: R5	5.73			
Scr: Missing; V fail: X4	0.52			
Scr: Missing; V fail: DM	1.04			
Scr: Missing; V fail: NR	7.29			
Scr: Missing; V fail: Missing	1.56			
Scr: NR; V fail: R5	0.52			
Scr: R5; V fail: R5	31.25			
Scr: R5; V fail: X4	4.17			
Scr: R5; V fail: DM	18.75			
Scr: R5; V fail: NR	22.92			
Scr: R5; V fail: Missing	6.25			

Notes:

[17] - N = subjects with virologic failure.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Emergence of Resistance to Maraviroc as Defined by Genotypic Changes in the V3 Loop of Glycoprotein 120 (gp 120)

End point title	Number of Subjects With Emergence of Resistance to Maraviroc as Defined by Genotypic Changes in the V3 Loop of Glycoprotein 120 (gp 120)

End point description:

Virus from subjects who experienced virologic failure was analyzed for resistance to maraviroc. Resistance testing was performed on archived samples of subjects which were available pre-treatment at time of virologic failure. For subjects who met definition of virologic failure during the trial, the sequencing of the V3 loop of HIV-1 viral envelope gp 120 was evaluated to identify any amino acid

changes concomitant with decreased susceptibility to maraviroc. Emergence of resistance was observed least frequently in virus from subjects who failed therapy with maraviroc-susceptible R5 virus, consistent with possibility that they failed because of poor adherence. Here "99999" in results section signifies data not available (NA) due to lack of any distinct mutational pattern for resistance in analyzed subjects.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	13[18]			
Units: Subjects	99999			

Notes:

[18] - Data not analysed due to lack of distinct mutational pattern for resistance in analysed subjects.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Reduced Maraviroc Susceptibility as Defined by Change From Baseline to Time of Virologic Failure in Inhibitory Concentration of 50% (IC 50) and Presence of Plateau

End point title	Number of Subjects With Reduced Maraviroc Susceptibility as Defined by Change From Baseline to Time of Virologic Failure in Inhibitory Concentration of 50% (IC 50) and Presence of Plateau

End point description:

Resistance to maravroc in viruses from subjects failing therapy with R5 virus was investigated using the in vitro phenotypic (drug susceptibility) assay. The number of subjects who failed with R5 virus were assessed successfully for maraviroc susceptibility at Baseline and Last on-treatment (Week 144). Samples were analyzed for change from Baseline to time of virologic failure in IC 50 and presence of plateau. A maximal percent inhibition (MPI) <95% established as a plateau in inhibition at high concentrations of maraviroc was used to identify viruses which had reduced phenotypic susceptibility to maraviroc.

End point type	Secondary

End point timeframe:

Baseline up to Week 144

End point values	Maraviroc			
Subject group type	Reporting group			
Number of subjects analysed	26[19]			
Units: Subjects	14			

Notes:

[19] - N= subjects who were assessed for maraviroc susceptibility

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment emergent adverse events were reported from time of first dose of study drug up to 30 days after last dose of study drug.

Adverse event reporting additional description:

The same event may appear as both an AE and a SAE. However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	MARAVIROC

Reporting group description:

Maraviroc 150 mg twice daily (BID), 600 mg BID, or 300 mg BID; dose administered depending on concomitant medications in combination with optimized background therapy (OBT) according to local standard of care.

Serious adverse events	MARAVIROC		
Total subjects affected by serious adverse events			
subjects affected / exposed	139 / 1032 (13.47%)		
number of deaths (all causes)	16		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anal cancer			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
B-cell lymphoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal squamous cell carcinoma			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Basal cell carcinoma			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hodgkin's disease				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Carcinoma in situ of penis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Penile squamous cell carcinoma				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostate cancer				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal cancer				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Gastric cancer				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Vascular disorders				
Hypertension				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hypertensive crisis				

subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Orthostatic hypotension			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Coronary artery bypass			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	7 / 1032 (0.68%)		
occurrences causally related to treatment / all	1 / 7		
deaths causally related to treatment / all	0 / 0		
Drug interaction			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Chills			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gait disturbance			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hyperthermia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Pyrexia				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Immune system disorders				
Immune reconstitution inflammatory syndrome				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Chronic obstructive pulmonary disease				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Acute respiratory failure				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Hypoxia				

subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Lung disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary oedema				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Anxiety disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Completed suicide				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hallucination, auditory				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Homicidal ideation				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Suicidal ideation				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Major depression				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Suicide attempt				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Investigations				
Blood alkaline phosphatase increased				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase increased				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
Blood glucose increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium test positive				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic enzyme increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Weight decreased				

subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Joint injury			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Overdose			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Post lumbar puncture syndrome			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rib fracture			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Toxicity to various agents			

subjects affected / exposed	3 / 1032 (0.29%)		
occurrences causally related to treatment / all	1 / 3		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Left ventricular failure			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Congestive cardiomyopathy			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Palpitations			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular tachycardia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac arrest			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Myocardial infarction				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 2			
Nervous system disorders				
Brain oedema				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Convulsion				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Disturbance in attention				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Presyncope			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 1032 (0.48%)		
occurrences causally related to treatment / all	0 / 8		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Vitreous floaters			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Visual impairment			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vision blurred			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Anogenital dysplasia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal fissure			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	7 / 1032 (0.68%)		
occurrences causally related to treatment / all	1 / 8		
deaths causally related to treatment / all	0 / 0		

Gastritis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Food poisoning				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lower gastrointestinal haemorrhage				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mallory-Weiss syndrome				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rectal polyp				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Peptic ulcer				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	1 / 1			
Hepatobiliary disorders				
Bile duct stone				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis cholestatic				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatocellular injury				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Hypertransaminasaemia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Hepatotoxicity				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Dermatitis allergic				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetic foot				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lichenoid keratosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psoriasis				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Rash			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Stevens-Johnson syndrome			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Urinary bladder polyp			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure acute			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Urinary retention			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Bone pain				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polyarthritis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myalgia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
AIDS dementia complex				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Bone tuberculosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchitis fungal				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermo-hypodermitis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dengue fever			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dysentery			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ear infection			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Extradural abscess			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatitis B			

subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Herpes zoster			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Intervertebral discitis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Leptospirosis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lower respiratory tract infection bacterial			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mastoiditis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningitis cryptococcal			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Mycobacterium avium complex infection			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mycobacterium kansasii infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis bacterial				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumococcal sepsis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia legionella				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Pseudomonas infection				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection bacterial			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences causally related to treatment / all	0 / 4		
deaths causally related to treatment / all	0 / 0		
Meningitis tuberculous			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
HIV infection			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pneumonia				
subjects affected / exposed	11 / 1032 (1.07%)			
occurrences causally related to treatment / all	0 / 12			
deaths causally related to treatment / all	0 / 1			
Septic shock				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Sepsis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Hypoglycaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lactic acidosis				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	MARAVIROC		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	700 / 1032 (67.83%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	6 / 1032 (0.58%)		
occurrences (all)	6		
Basal cell carcinoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	2		
Bowen's disease			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Haemangioma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Kaposi's sarcoma			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Lipoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Oral papilloma			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences (all)	6		
Prostatic adenoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Penile wart			

subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Skin papilloma			
subjects affected / exposed	9 / 1032 (0.87%)		
occurrences (all)	11		
Seborrhoeic keratosis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Rectal cancer			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Squamous cell carcinoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Squamous cell carcinoma of the tongue			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Thyroid neoplasm			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Testicular neoplasm			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Uterine leiomyoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Flushing			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Haematoma			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Haemorrhage				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hot flush				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hypertension				
subjects affected / exposed	22 / 1032 (2.13%)			
occurrences (all)	23			
Hypertensive crisis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Orthostatic hypotension				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Hypotension				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pallor				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Peripheral venous disease				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Phlebitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Thrombophlebitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Venoocclusive disease				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Venous thrombosis				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Surgical and medical procedures			
Circumcision			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Papilloma excision			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Dental implantation			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Prophylaxis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Tooth extraction			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
General disorders and administration site conditions			
Adverse drug reaction			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Asthenia			
subjects affected / exposed	22 / 1032 (2.13%)		
occurrences (all)	23		
Chest discomfort			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Chest pain			
subjects affected / exposed	10 / 1032 (0.97%)		
occurrences (all)	10		
Chills			
subjects affected / exposed	5 / 1032 (0.48%)		
occurrences (all)	5		
Crepitations			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Facial pain				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Fat tissue increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Fatigue				
subjects affected / exposed	24 / 1032 (2.33%)			
occurrences (all)	29			
Feeling hot				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Feeling jittery				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Injection site nodule				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Influenza like illness				
subjects affected / exposed	14 / 1032 (1.36%)			
occurrences (all)	14			
Injection site swelling				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Injection site reaction				
subjects affected / exposed	8 / 1032 (0.78%)			
occurrences (all)	8			
Local swelling				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Malaise				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Mucosal inflammation				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Necrosis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Nodule			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences (all)	4		
Oedema			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Oedema peripheral			
subjects affected / exposed	9 / 1032 (0.87%)		
occurrences (all)	11		
Pain			
subjects affected / exposed	15 / 1032 (1.45%)		
occurrences (all)	15		
Peripheral swelling			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Thirst			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	50 / 1032 (4.84%)		
occurrences (all)	56		
Ulcer			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Allergy to arthropod bite			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		

Food allergy			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Seasonal allergy			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Immune reconstitution inflammatory syndrome			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Hypersensitivity			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	3		
Social circumstances			
Alcohol use			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Amenorrhoea			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Bartholin's cyst			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Benign prostatic hyperplasia			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Breast cyst			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Breast pain			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Cervical polyp			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Erectile dysfunction				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	10			
Galactorrhoea				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	2			
Genital ulceration				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	2			
Genital lesion				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gynaecomastia				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Ovarian cyst				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Oedema genital				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Metrorrhagia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pelvic pain				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Prostatism				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Prostatic pain				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Premenstrual syndrome				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Prostatitis			
subjects affected / exposed	7 / 1032 (0.68%)		
occurrences (all)	8		
Pruritus genital			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Scrotal ulcer			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Retrograde ejaculation			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Testicular swelling			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	3		
Testicular pain			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Uterine cyst			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Vulvovaginal discomfort			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	2		
Vaginal discharge			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	6 / 1032 (0.58%)		
occurrences (all)	9		
Asthmatic crisis			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Chronic obstructive pulmonary disease				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Catarrh				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Bronchospasm				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Dry throat				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Cyanosis central				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Cough				
subjects affected / exposed	47 / 1032 (4.55%)			
occurrences (all)	61			
Dysphonia				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Dyspnoea				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	12			
Dyspnoea exertional				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Emphysema				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Epistaxis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			

Haemoptysis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hiccups				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Nasal congestion				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Lung disorder				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Oropharyngeal pain				
subjects affected / exposed	7 / 1032 (0.68%)			
occurrences (all)	7			
Interstitial lung disease				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	4			
Pharyngeal erythema				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	6			
Orthopnoea				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pharyngeal ulceration				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Pharyngeal disorder				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Pneumonitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pleurisy				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Productive cough				
subjects affected / exposed	7 / 1032 (0.68%)			
occurrences (all)	7			
Respiratory failure				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Respiratory disorder				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Rales				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Rhinorrhoea				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	12			
Rhinitis allergic				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Sinus congestion				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Respiratory tract congestion				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Tonsillar disorder				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Tonsillar hypertrophy				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Sleep apnoea syndrome				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Tonsillar ulcer				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences (all)	4		
Aggression			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Agitation			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Anxiety			
subjects affected / exposed	23 / 1032 (2.23%)		
occurrences (all)	24		
Bulimia nervosa			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Bipolar I disorder			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	2		
Confusional state			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Depressed mood			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Depression			
subjects affected / exposed	20 / 1032 (1.94%)		
occurrences (all)	21		
Euphoric mood			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Dysphoria			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Disorientation			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hallucination				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hallucination, auditory				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Initial insomnia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Insomnia				
subjects affected / exposed	32 / 1032 (3.10%)			
occurrences (all)	35			
Libido decreased				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Irritability				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Libido disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Mental disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Mood altered				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Nervousness				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Sleep disorder				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Stereotypy				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Thinking abnormal			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Stress			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Tic			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Withdrawal syndrome			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Hepatobiliary disorders			
Cholestasis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Cholelithiasis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Hepatic steatosis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Hepatitis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Hepatocellular injury			
subjects affected / exposed	5 / 1032 (0.48%)		
occurrences (all)	5		
Hepatitis acute			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Hepatomegaly			
subjects affected / exposed	9 / 1032 (0.87%)		
occurrences (all)	9		

Hyperbilirubinaemia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Hypertransaminasaemia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Jaundice			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences (all)	4		
Liver disorder			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	13 / 1032 (1.26%)		
occurrences (all)	18		
Amylase increased			
subjects affected / exposed	11 / 1032 (1.07%)		
occurrences (all)	15		
Aspartate aminotransferase abnormal			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Aspartate aminotransferase increased			
subjects affected / exposed	9 / 1032 (0.87%)		
occurrences (all)	9		
Blood creatine increased			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Blood cholesterol increased			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Blood alkaline phosphatase			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Blood creatine phosphokinase increased			

subjects affected / exposed	8 / 1032 (0.78%)			
occurrences (all)	8			
Blood creatinine increased				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Blood glucose abnormal				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Blood glucose increased				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Blood lactate dehydrogenase increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Blood iron decreased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Blood phosphorus decreased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	2			
Blood pressure increased				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Blood sodium increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Blood triglycerides increased				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	7			
Blood uric acid increased				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Blood urine present				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Cardiac function test abnormal				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Body temperature increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Cardiac murmur				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Eosinophil count increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Carotid bruit				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gamma-glutamyltransferase increased				
subjects affected / exposed	12 / 1032 (1.16%)			
occurrences (all)	15			
Glycosylated haemoglobin increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Helicobacter test positive				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Haemoglobin decreased				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hepatic enzyme increased				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hepatitis B DNA increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hepatitis B antibody positive				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hepatitis B surface antigen positive				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Hepatitis B virus test positive				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Human papilloma virus test positive				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Lipase increased				
subjects affected / exposed	7 / 1032 (0.68%)			
occurrences (all)	7			
Liver function test abnormal				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Low density lipoprotein increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Lymph node palpable				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	3			
Murphy's sign positive				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Occult blood positive				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Prostatic specific antigen increased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Platelet count decreased				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Physical examination				

subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Urine output decreased			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Treponema test positive			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Transaminases increased			
subjects affected / exposed	6 / 1032 (0.58%)		
occurrences (all)	6		
Waist circumference increased			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	12 / 1032 (1.16%)		
occurrences (all)	13		
Weight increased			
subjects affected / exposed	11 / 1032 (1.07%)		
occurrences (all)	12		
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Ankle fracture			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Arthropod bite			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Bone fissure			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Clavicle fracture			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Contusion				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	4			
Fall				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Excoriation				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Epicondylitis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Foot fracture				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Foreign body in eye				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Joint injury				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Head injury				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Ligament rupture				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Laceration				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Ligament sprain				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Limb injury				

subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Muscle strain			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Periorbital haematoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Overdose			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Post procedural haematoma			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Radius fracture			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Skeletal injury			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Sunburn			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Thermal burn			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Upper limb fracture			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Congenital, familial and genetic disorders			
Preauricular cyst			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Dysmorphism			

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Accessory spleen			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Cardiac failure congestive			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Cyanosis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Extrasystoles			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Left atrial dilatation			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Hyperdynamic left ventricle			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Pericardial effusion			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Palpitations			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Sinus bradycardia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	5 / 1032 (0.48%)		
occurrences (all)	5		

Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Amnesia			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences (all)	4		
Carpal tunnel syndrome			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Ataxia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Aphasia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Central nervous system lesion			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	26 / 1032 (2.52%)		
occurrences (all)	27		
Decreased vibratory sense			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Cerebral atrophy			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Epilepsy			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Dysarthria			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Dysaesthesia			

subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Headache				
subjects affected / exposed	66 / 1032 (6.40%)			
occurrences (all)	70			
Hyperaesthesia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypersomnia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypoaesthesia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	2			
Lethargy				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Memory impairment				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Loss of consciousness				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Migraine				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Neuralgia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Nerve root compression				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Muscle contractions involuntary				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Neuropathy peripheral				

subjects affected / exposed	14 / 1032 (1.36%)		
occurrences (all)	14		
Paraesthesia			
subjects affected / exposed	7 / 1032 (0.68%)		
occurrences (all)	7		
Radiculopathy			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Presyncope			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Sensory disturbance			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Sciatica			
subjects affected / exposed	6 / 1032 (0.58%)		
occurrences (all)	6		
Serotonin syndrome			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Sleep phase rhythm disturbance			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Somnolence			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Tension headache			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
VIIth nerve paralysis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Blood and lymphatic system disorders			

Agranulocytosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Anaemia				
subjects affected / exposed	18 / 1032 (1.74%)			
occurrences (all)	19			
Eosinophilia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Bone marrow failure				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Iron deficiency anaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Leukocytosis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Leukopenia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Lymphadenopathy				
subjects affected / exposed	18 / 1032 (1.74%)			
occurrences (all)	19			
Microcytic anaemia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Neutropenia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Microcytosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Polycythaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Splenomegaly			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Thrombocytopenia			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences (all)	4		
Ear pain			
subjects affected / exposed	7 / 1032 (0.68%)		
occurrences (all)	8		
Cerumen impaction			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Tympanic membrane hyperaemia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	12 / 1032 (1.16%)		
occurrences (all)	15		
Eye disorders			
Blepharitis			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Blindness unilateral			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Cataract			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Conjunctival haemorrhage			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Conjunctivitis allergic			

subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Dry eye				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Exophthalmos				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Eye swelling				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Eye irritation				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Glaucoma				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Foreign body sensation in eyes				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Metamorphopsia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Ocular icterus				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Punctate keratitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pupils unequal				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Uveitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Vision blurred				

subjects affected / exposed	7 / 1032 (0.68%)		
occurrences (all)	7		
Visual impairment			
subjects affected / exposed	5 / 1032 (0.48%)		
occurrences (all)	5		
Visual acuity reduced			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Vitreous floaters			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Vitreous detachment			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	20 / 1032 (1.94%)		
occurrences (all)	23		
Abdominal distension			
subjects affected / exposed	16 / 1032 (1.55%)		
occurrences (all)	16		
Abdominal pain lower			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Abdominal pain upper			
subjects affected / exposed	14 / 1032 (1.36%)		
occurrences (all)	19		
Anal fistula			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Abdominal tenderness			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		

Anal polyp				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Anogenital dysplasia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Anal ulcer				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Anorectal discomfort				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Anorectal disorder				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Aphthous stomatitis				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Cheilitis				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Colitis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Colitis ulcerative				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Defaecation urgency				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Constipation				
subjects affected / exposed	35 / 1032 (3.39%)			
occurrences (all)	35			
Dental caries				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			

Diarrhoea haemorrhagic				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Diarrhoea				
subjects affected / exposed	93 / 1032 (9.01%)			
occurrences (all)	109			
Dry mouth				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Dyspepsia				
subjects affected / exposed	13 / 1032 (1.26%)			
occurrences (all)	13			
Dysphagia				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	7			
Eructation				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Faecal incontinence				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Faeces soft				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Flatulence				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	10			
Food poisoning				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Functional gastrointestinal disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gastritis				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	10			

Gastric disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gastrointestinal disorder				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Gastrooesophageal reflux disease				
subjects affected / exposed	9 / 1032 (0.87%)			
occurrences (all)	10			
Gastrointestinal pain				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Glossitis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Haematochezia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Haemorrhoids				
subjects affected / exposed	12 / 1032 (1.16%)			
occurrences (all)	15			
Haemorrhoidal haemorrhage				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Haemorrhoids thrombosed				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hyperchlorhydria				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypoaesthesia oral				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Inguinal hernia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Intestinal obstruction				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Irritable bowel syndrome				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Large intestine polyp				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Mouth ulceration				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Odynophagia				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Nausea				
subjects affected / exposed	60 / 1032 (5.81%)			
occurrences (all)	67			
Oesophagitis				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Oral discomfort				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Oral disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Oral lichen planus				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Painful defaecation				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	3			
Paraesthesia oral				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Parotid gland enlargement subjects affected / exposed occurrences (all)	2 / 1032 (0.19%) 2		
Proctalgia subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Rectal haemorrhage subjects affected / exposed occurrences (all)	6 / 1032 (0.58%) 6		
Tongue discolouration subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 2		
Salivary gland cyst subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Tongue disorder subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Toothache subjects affected / exposed occurrences (all)	2 / 1032 (0.19%) 2		
Tongue ulceration subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Umbilical hernia subjects affected / exposed occurrences (all)	2 / 1032 (0.19%) 2		
Uvulitis subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Vomiting subjects affected / exposed occurrences (all)	34 / 1032 (3.29%) 41		
Skin and subcutaneous tissue disorders Alopecia			

subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	7			
Actinic keratosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	2			
Acne				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Dandruff				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	3			
Dermatitis				
subjects affected / exposed	8 / 1032 (0.78%)			
occurrences (all)	8			
Dermal cyst				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Drug eruption				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Dermatosis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Dermatitis contact				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Dermatitis acneiform				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Eosinophilic pustular folliculitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Eczema				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	5			
Erythema				

subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Dry skin				
subjects affected / exposed	9 / 1032 (0.87%)			
occurrences (all)	9			
Facial wasting				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hand dermatitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Erythema multiforme				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Lichen planus				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Intertrigo				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Ingrowing nail				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hyperhidrosis				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Lipoatrophy				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Lipohypertrophy				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Lipodystrophy acquired				
subjects affected / exposed	7 / 1032 (0.68%)			
occurrences (all)	7			
Papule				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Onychoclasis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Night sweats				
subjects affected / exposed	7 / 1032 (0.68%)			
occurrences (all)	7			
Nail ridging				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Penile ulceration				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Polymorphic light eruption				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Prurigo				
subjects affected / exposed	8 / 1032 (0.78%)			
occurrences (all)	12			
Psoriasis				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Pruritus				
subjects affected / exposed	22 / 1032 (2.13%)			
occurrences (all)	25			
Purpura				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Rash maculo-papular				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Rash macular				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Rash erythematous				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	2			
Rash				
subjects affected / exposed	45 / 1032 (4.36%)			
occurrences (all)	47			
Rash papular				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Rash pruritic				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Rash vesicular				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Seborrhoea				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Seborrhoeic dermatitis				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	7			
Skin exfoliation				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Skin fibrosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Skin fragility				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Skin haemorrhage				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Skin irritation				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Skin induration				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Skin lesion			
subjects affected / exposed	6 / 1032 (0.58%)		
occurrences (all)	8		
Skin mass			
subjects affected / exposed	10 / 1032 (0.97%)		
occurrences (all)	10		
Skin reaction			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Skin ulcer			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Urticaria			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Swelling face			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Renal and urinary disorders			
Bladder disorder			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Calculus bladder			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Calculus ureteric			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Dysuria			
subjects affected / exposed	9 / 1032 (0.87%)		
occurrences (all)	10		
Chromaturia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		

Haematuria				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	5			
Microalbuminuria				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Micturition disorder				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Micturition urgency				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Nephritis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Nephroangiosclerosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Nephrolithiasis				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Nephropathy				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Polyuria				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Pollakiuria				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	6			
Nocturia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Renal cyst				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Renal failure subjects affected / exposed occurrences (all)	4 / 1032 (0.39%) 4		
Renal impairment subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Renal failure acute subjects affected / exposed occurrences (all)	2 / 1032 (0.19%) 2		
Ureteral disorder subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Renal pain subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Urinary hesitation subjects affected / exposed occurrences (all)	3 / 1032 (0.29%) 3		
Urinary incontinence subjects affected / exposed occurrences (all)	3 / 1032 (0.29%) 3		
Urinary tract disorder subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Endocrine disorders			
Goitre subjects affected / exposed occurrences (all)	2 / 1032 (0.19%) 2		
Hypogonadism subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Inappropriate antidiuretic hormone secretion subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Hypothyroidism			

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	34 / 1032 (3.29%)		
occurrences (all)	34		
Arthritis			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	5		
Bone disorder			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	45 / 1032 (4.36%)		
occurrences (all)	51		
Arthropathy			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Bone pain			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Coccydynia			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Bursitis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Bursa disorder			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	3 / 1032 (0.29%)		
occurrences (all)	3		
Enthesopathy			

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Costochondritis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gouty arthritis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Groin pain				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypercreatinaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Intervertebral disc protrusion				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Joint stiffness				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Joint range of motion decreased				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Joint swelling				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Muscle atrophy				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Limb discomfort				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Muscle contracture				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Muscle spasms				

subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Musculoskeletal chest pain				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Musculoskeletal pain				
subjects affected / exposed	11 / 1032 (1.07%)			
occurrences (all)	11			
Musculoskeletal stiffness				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Myalgia				
subjects affected / exposed	20 / 1032 (1.94%)			
occurrences (all)	21			
Neck pain				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Osteitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Osteoarthritis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Osteopenia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Osteonecrosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pain in extremity				
subjects affected / exposed	20 / 1032 (1.94%)			
occurrences (all)	24			
Polyarthritis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Plantar fasciitis				

subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Rotator cuff syndrome			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Spinal pain			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Tendon pain			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Synovial cyst			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	2		
Tendonitis			
subjects affected / exposed	4 / 1032 (0.39%)		
occurrences (all)	4		
Tenosynovitis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Torticollis			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Infections and infestations			
Abscess			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Abscess limb			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Acarodermatitis			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Acute hepatitis C			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		

Anal abscess				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Amoebic dysentery				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	2			
Acute sinusitis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Anal fungal infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Anorectal human papilloma virus infection				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Body tinea				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Bronchiolitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Bronchitis				
subjects affected / exposed	67 / 1032 (6.49%)			
occurrences (all)	79			
Bronchitis bacterial				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Campylobacter gastroenteritis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Candida infection				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Cellulitis				

subjects affected / exposed	8 / 1032 (0.78%)			
occurrences (all)	8			
Chronic hepatitis C				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Chronic sinusitis				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	5			
Conjunctivitis				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	10			
Conjunctivitis viral				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Cystitis				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Cytomegalovirus infection				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Diverticulitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Dermo-hypodermitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Ear infection				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Extrapulmonary tuberculosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Eye infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Fungal infection				

subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Folliculitis				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Fungal skin infection				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Furuncle				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Gastroenteritis viral				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Gastroenteritis				
subjects affected / exposed	17 / 1032 (1.65%)			
occurrences (all)	17			
Gastrointestinal infection				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Gastrointestinal viral infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Genital abscess				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Genital herpes				
subjects affected / exposed	11 / 1032 (1.07%)			
occurrences (all)	13			
Genital herpes simplex				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Genital infection fungal				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Genitourinary chlamydia infection				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gonorrhoea				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gingivitis				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Helicobacter gastritis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Haemophilus infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hepatitis A				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hepatitis B				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Hepatitis C				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Herpes simplex				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	11			
Herpes virus infection				
subjects affected / exposed	10 / 1032 (0.97%)			
occurrences (all)	10			
Herpes zoster				
subjects affected / exposed	18 / 1032 (1.74%)			
occurrences (all)	19			
Hordeolum				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Impetigo				

subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Infection				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Infected bites				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Infestation				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Laryngitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Influenza				
subjects affected / exposed	29 / 1032 (2.81%)			
occurrences (all)	34			
Localised infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Lower respiratory tract infection				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Mastitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Lymphangitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Mastoiditis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Meningitis aseptic				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Molluscum contagiosum				

subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Mycotic corneal ulcer				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	39 / 1032 (3.78%)			
occurrences (all)	43			
Oesophageal candidiasis				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	7			
Onychomycosis				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	9			
Oral candidiasis				
subjects affected / exposed	28 / 1032 (2.71%)			
occurrences (all)	41			
Oral fungal infection				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Oral herpes				
subjects affected / exposed	17 / 1032 (1.65%)			
occurrences (all)	18			
Oral hairy leukoplakia				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Oral infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Otitis externa				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Orchitis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Otitis media				

subjects affected / exposed	7 / 1032 (0.68%)			
occurrences (all)	8			
Otitis media acute				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Paronychia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Periodontitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pharyngitis				
subjects affected / exposed	22 / 1032 (2.13%)			
occurrences (all)	25			
Pneumococcal infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pneumonia				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	7			
Progressive multifocal leukoencephalopathy				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Prostatitis Escherichia coli				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pulmonary tuberculosis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Purulent discharge				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Pyelonephritis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			

Pyuria				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Rash pustular				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Respiratory tract infection				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	6			
Respiratory tract infection viral				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Rhinitis				
subjects affected / exposed	13 / 1032 (1.26%)			
occurrences (all)	13			
Scrotal infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Secondary syphilis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Sepsis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Shigella infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Sinusitis				
subjects affected / exposed	28 / 1032 (2.71%)			
occurrences (all)	28			
Skin infection				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Staphylococcal skin infection				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			

Staphylococcal infection				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Syphilis				
subjects affected / exposed	7 / 1032 (0.68%)			
occurrences (all)	7			
Tinea infection				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	4			
Tinea cruris				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Tinea pedis				
subjects affected / exposed	5 / 1032 (0.48%)			
occurrences (all)	5			
Tinea versicolour				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Tooth abscess				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	3			
Tooth infection				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Toxoplasmosis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Tracheitis				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Upper respiratory tract infection				
subjects affected / exposed	41 / 1032 (3.97%)			
occurrences (all)	62			
Urethritis				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			

Urethritis gonococcal subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Urinary tract infection bacterial subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Urinary tract infection subjects affected / exposed occurrences (all)	17 / 1032 (1.65%) 19		
Urinary tract infection enterococcal subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Viral infection subjects affected / exposed occurrences (all)	6 / 1032 (0.58%) 7		
Urinary tract infection fungal subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Viral pharyngitis subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Viral sinusitis subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Vulvovaginal candidiasis subjects affected / exposed occurrences (all)	4 / 1032 (0.39%) 4		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 1032 (0.19%) 2		
Wound infection subjects affected / exposed occurrences (all)	1 / 1032 (0.10%) 1		
Metabolism and nutrition disorders Cell death			

subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Decreased appetite				
subjects affected / exposed	9 / 1032 (0.87%)			
occurrences (all)	11			
Dehydration				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Diabetes mellitus				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Dyslipidaemia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hyperamylasaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Gout				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Folate deficiency				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypercalcaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypercholesterolaemia				
subjects affected / exposed	4 / 1032 (0.39%)			
occurrences (all)	4			
Hyperferritinaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hyperglycaemia				
subjects affected / exposed	3 / 1032 (0.29%)			
occurrences (all)	5			
Hyperkalaemia				

subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypertriglyceridaemia				
subjects affected / exposed	25 / 1032 (2.42%)			
occurrences (all)	34			
Hyperlipidaemia				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	7			
Hypocalcaemia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hyperuricaemia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hypocholesterolaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Hypoglycaemia				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hypokalaemia				
subjects affected / exposed	6 / 1032 (0.58%)			
occurrences (all)	6			
Impaired fasting glucose				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	2			
Hypovolaemia				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Metabolic syndrome				
subjects affected / exposed	1 / 1032 (0.10%)			
occurrences (all)	1			
Malnutrition				
subjects affected / exposed	2 / 1032 (0.19%)			
occurrences (all)	3			
Increased appetite				

subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Selenium deficiency			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Vitamin D deficiency			
subjects affected / exposed	2 / 1032 (0.19%)		
occurrences (all)	2		
Vitamin C deficiency			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		
Zinc deficiency			
subjects affected / exposed	1 / 1032 (0.10%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 January 2007	The purpose of this global amendment was to: 1. add a follow up visit 30 days following study drug discontinuation, 2. undertake follow-up of all treatment emergent grade 3 or 4 Adverse Events regardless of causality, until the event resolves or stabilizes at a level acceptable to the investigator. 3. provide information regarding blood sample collection, labelling, storage and study of specified genes for the pharmacogenomics analysis, and 4. include those subjects in a safety registry, who participated in this expanded access program and who continue to receive commercially available maraviroc after study completion.
11 June 2007	This global amendment was added in order to: 1. include smoking assessment and cardiovascular risk assessment to the Schedule of Events, 2. separate the vital signs assessments in the Schedule of Events to specify supine and standing blood pressure for vital signs, 3. move the collection of the pharmacogenomics sample from the Screening visit to the Baseline visit, 4. remove St. John's wort as a contraindicated medication, 5. add criteria for study drug interruption or discontinuation due to laboratory abnormalities, and 6. update the AE reporting period in order that it began from the time of taking the first dose of study drug rather than from time of consent.
29 August 2007	This global amendment was added in order to: 1. add additional Exclusion Criterion to exclude subjects with hypersensitivity to peanut, and 2. include clarification for inclusion of subjects with abnormal laboratory results at the Screening visit.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Viral loads were not available for subjects uniformly as this expanded access study followed local country guidelines and practices that could vary significantly between countries, and testing frequency may have been affected by insurance status.

Notes: