Clinical trial results:
Intermediate and high risk localized, completely resected, gastrointestinal stromal tumors (GIST) expressing KIT receptor: a controlled randomized trial on adjuvant Imatinib mesylate (Glivec) versus no further therapy after complete surgery

Summary

EudraCT number	2004-001810-16
Trial protocol	DE DK GB ES BE IT
Global end of trial date	12 July 2017

Results information

Result version number	v1 (current)
This version publication date	15 April 2018
First version publication date	15 April 2018

Trial information

Trial identification

Sponsor protocol code	62024

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00103168
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	EORTC HQ
Sponsor organisation address	Avenue Emmanuel Mounier 83, Brussels, Belgium, 1200
Public contact	Project, Budget and Regulatory Depa, European Organisation for Research and Treatment of Cancer, +32 27741044, regulatory@eortc.be
Scientific contact	Project, Budget and Regulatory Depa, European Organisation for Research and Treatment of Cancer, +32 27741044, regulatory@eortc.be

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 June 2017
Global end of trial reached?	Yes
Global end of trial date	12 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess whether Imatinib mesylate, as an adjunct to complete surgery, is able to improve prognosis of patients with intermediate and high-risk, localized GIST.

Protection of trial subjects:

- Prophylactic use of loperamide (e.g., Imodium®) is recommended for patients experiencing Grade 1 or 2 diarrhea.
- Low-molecular weight heparin (Coumadin 1 mg QD) is permitted for prophylaxis of central venous catheter thrombosis, at the discretion of the treating physician.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 January 2005
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	Spain: 80
Country: Number of subjects enrolled	United Kingdom: 84
Country: Number of subjects enrolled	Belgium: 14
Country: Number of subjects enrolled	Denmark: 7
Country: Number of subjects enrolled	France: 266
Country: Number of subjects enrolled	Germany: 126
Country: Number of subjects enrolled	Italy: 127
Country: Number of subjects enrolled	Australia: 67
Country: Number of subjects enrolled	Netherlands: 63
Country: Number of subjects enrolled	New Zealand: 7
Country: Number of subjects enrolled	Poland: 60
Country: Number of subjects enrolled	Singapore: 7
Worldwide total number of subjects	908
EEA total number of subjects	827

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	604
From 65 to 84 years	302
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Recruitment period: between 06/01/2005 and 15/10/2008.
territories: 12 countries (9 EU countries and 3 non EU)

Pre-assignment

Screening details:

- Histologically proven diagnosis of GIST, with positive immunostaining for KIT (CD117), documented by polyclonal DAKO antibody staining.
- Risk of relapse documented on the surgical specimen as falling within the "high-risk" category or the "intermediate-risk" category.
- Surgery performed from 2 weeks to 3 months before randomization

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Observation

Arm description:

Follow-up after surgery without further antitumoral therapy

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Imatinib mesylate

Arm description:

Imatinib mesylate (400mg/day) during 2 years after surgery

Arm type	Experimental
Investigational medicinal product name	Imatinib mesylate
Investigational medicinal product code	NSC-716051
Other name	STI-571 , Gleevec, Glivec
Pharmaceutical forms	Powder for oral solution
Routes of administration	Oral use

Dosage and administration details:

400mg/day during 2 years

Number of subjects in period 1	Observation	Imatinib mesylate
Started	454	454
Completed	454	454

Period 2	
Period 2 title	On-study
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms	
Are arms mutually exclusive?	Yes
Arm title	Observation

Arm description:

Follow-up after surgery without further antitumoral therapy

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Imatinib mesylate

Arm description:

Imatinib mesylate (400mg/day) during 2 years after surgery

Arm type	Experimental
Investigational medicinal product name	Imatinib mesylate
Investigational medicinal product code	NSC-716051
Other name	STI-571 , Gleevec, Glivec
Pharmaceutical forms	Powder for oral solution
Routes of administration	Oral use

Dosage and administration details:

400mg/day during 2 years

Number of subjects in period 2	Observation	Imatinib mesylate
Started	454	454
Completed	453	336
Not completed	1	118
Consent withdrawn by subject	-	22
Wrong diagnosis, second cancer, concurrent disease	-	15
Adverse event, non-fatal	-	56
Did not start the treatment	-	5
Treated with Imatinib in another center	1	-
Lack of efficacy	-	20

Baseline characteristics

Reporting groups	
Reporting group title	Observation
Reporting group description:	
Follow-up after surgery without further antitumoral therapy	
Reporting group title	Imatinib mesylate
Reporting group description:	
Imatinib mesylate (400mg/day) during 2 years after surgery	

Reporting group values	Observation	Imatinib mesylate	Total
Number of subjects	454	454	908
Age categorical			
Age in 4 categories			
Units: Subjects			
<= 20 years	1	3	4
21-40 years	29	52	81
41-60 years	223	189	412
> 60 years	201	210	411
Age continuous			
Units: years			
median	58	59	
inter-quartile range (Q1-Q3)	49 to 68	48 to 67	-
Gender categorical			
Units: Subjects			
Female	220	222	442
Male	234	232	466
Performance status			
Units: Subjects			
PS=0	380	399	779
PS=1	74	54	128
PS=2	0	1	1

End points

End points reporting groups	
Reporting group title	Observation
Reporting group description: Follow-up after surgery without further antitumoral therapy	
Reporting group title	Imatinib mesylate
Reporting group description: Imatinib mesylate (400mg/day) during 2 years after surgery	
Reporting group title	Observation
Reporting group description: Follow-up after surgery without further antitumoral therapy	
Reporting group title	Imatinib mesylate
Reporting group description: Imatinib mesylate (400mg/day) during 2 years after surgery	

Primary: imatinib monotherapy failure free survival (IFS)	
End point title	imatinib monotherapy failure free survival (IFS)
End point description: Imatinib monotherapy Failure free Survival (IFS) is measured from the date of randomization to the date of occurrence of any of the following events: 1)start of new systemic treatment 2)combination of imatinib with a new systemic treatment 3)death from any cause If none of these events has occurred, patients will be censored at the date of last follow-up or at the date of clinical cut-off whichever occurs the first.	
End point type	Primary
End point timeframe: Follow-up will be performed every 3 months until 2 years from randomization have elapsed, then every 4 months until 5 years have elapsed, and thereafter at least annually, at the discretion of the responsible physician.	

End point values	Observation	Imatinib mesylate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	454	454		
Units: events				
Imatinib failure free	348	358		
Imatinib failure: start of new systemic treatment	76	66		
Imatinib failure: death without new systemic treat	30	30		

Attachments (see zip file)	
	IFS - Adjusted/IFS.png IFS - Unadjusted (per protocol)/IFS 2.png

Statistical analyses

Statistical analysis title	Imatinib Failure free Survival (IFS - Adjusted)
Statistical analysis description:	
Survival analysis at 5 years and at 10 years	
Comparison groups	Imatinib mesylate v Observation
Number of subjects included in analysis	908
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.307 [1]
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.866
Confidence interval	
level	95.7 %
sides	2-sided
lower limit	0.651
upper limit	1.152

Notes:

[1] - Adjusted by the stratification factors at randomization (Risk category, Resection, Tumor site)

Statistical analysis title	Imatinib Failure free Survival (IFS - Unadjusted)
Statistical analysis description:	
Unadjusted analysis (by protocol)	
Comparison groups	Observation v Imatinib mesylate
Number of subjects included in analysis	908
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.345
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.88
Confidence interval	
level	95.7 %
sides	2-sided
lower limit	0.66
upper limit	1.16

Secondary: Relapse free Survival

End point title	Relapse free Survival
End point description:	
Relapse free interval is measured from the date of randomization to the date of relapse. Patients alive and relapse free are censored at the date of last follow-up or at the date of clinical cut-off whichever occurs the first.	
End point type	Secondary
End point timeframe:	
The same timeframe than the one used for primary endpoint	

End point values	Observation	Imatinib mesylate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	454	454		
Units: Events				
No relapse	283	299		
Relapse or death	171	155		

Attachments (see zip file)	RFS - Adjusted/RFS.png

Statistical analyses

Statistical analysis title	Relaspe free survival (RFS - Adjusted)
Statistical analysis description: Adjusted for stratification factors (Risk category, Resection, Tumor Site)	
Comparison groups	Imatinib mesylate v Observation
Number of subjects included in analysis	908
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.713
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.573
upper limit	0.887

Statistical analysis title	Relapse free Survival (RFS - Unadjusted)
Statistical analysis description: As prescribed per protocol	
Comparison groups	Observation v Imatinib mesylate
Number of subjects included in analysis	908
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.013
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.76

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.95

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

Overall survival is measured from the date of randomization to the date of death, whatever the cause. Alive patients are censored at the date of last follow-up or at the date of clinical cut-off whichever occurs the first.

End point type	Secondary

End point timeframe:

The same than the one used for the primary endpoint

End point values	Observation	Imatinib mesylate		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	454	454		
Units: Events				
Alive	285	296		
Lost to follow-up	86	83		
Death	83	75		

Attachments (see zip file)	OS - adjusted/OS adj.png

Statistical analyses

Statistical analysis title	Overall survival (OS - Adjusted)

Statistical analysis description:

Adjusted for stratification factors (Risk Category, Resection, Tumor Site)

Comparison groups	Observation v Imatinib mesylate
Number of subjects included in analysis	908
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.429
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.882

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.645
upper limit	1.205

Statistical analysis title	Overall Survival (OS - Unadjusted)
Statistical analysis description: As prescribed in the protocol	
Comparison groups	Observation v Imatinib mesylate
Number of subjects included in analysis	908
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.476
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	1.22

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected on a CRF to be submitted at pre-specified timepoint

Adverse event reporting additional description:

CRF for AEs contains pre-specified items + additional boxes for all "other" AEs. (xx% AEs are reported as "other" and are not reported as not available from the list of SOC).
AEs are evaluated using CTC grading, SAEs using MedDra. Non-SAEs has not been collected specifically, all AEs will be reported in non-SAE section.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19

Reporting groups

Reporting group title	Observation

Reporting group description:

Observation

Reporting group title	Imatinib Mesylate

Reporting group description:

Imatinib Mesylate

Serious adverse events	Observation	Imatinib Mesylate	
Total subjects affected by serious adverse events			
subjects affected / exposed	41 / 454 (9.03%)	84 / 454 (18.50%)	
number of deaths (all causes)	83	75	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BENIGN OVARIAN TUMOUR			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRAIN NEOPLASM			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BREAST CANCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
BRONCHIAL CARCINOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHRONIC LYMPHOCYTIC LEUKAEMIA STAGE 0			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DESMOID TUMOUR			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ENDOMETRIAL ADENOCARCINOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROINTESTINAL STROMAL TUMOUR			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG NEOPLASM MALIGNANT			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
MALIGNANT MELANOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALIGNANT NEOPLASM PROGRESSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PAPILLARY THYROID CANCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PENILE CANCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PROSTATE CANCER			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CANCER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL CELL CARCINOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SCHWANNOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SQUAMOUS CELL CARCINOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
TUMOUR HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
UTERINE LEIOMYOMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vascular disorders			
HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOVOLAEMIC SHOCK			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VARICOSE VEIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
CORONARY ARTERY BYPASS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
EXPLORATIVE LAPAROTOMY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RADIOACTIVE IODINE THERAPY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SURGERY			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
CHEST PAIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DISEASE RECURRENCE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
FATIGUE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENERAL PHYSICAL HEALTH DETERIORATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
MULTI-ORGAN FAILURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 454 (0.44%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
NODULE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OEDEMA PERIPHERAL			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PYREXIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
ENDOMETRIOSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
GENITAL HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VAGINAL PROLAPSE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DYSPNOEA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LUNG DISORDER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
PLEURAL EFFUSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PNEUMONITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY EMBOLISM			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PULMONARY FIBROSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

RESPIRATORY DISTRESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
DEPRESSED MOOD			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
DEPRESSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MAJOR DEPRESSION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ASPARTATE AMINOTRANSFERASE INCREASED			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OESOPHAGOGASTRODUODENOSCOP			

Y			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
FEMUR FRACTURE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
POSTOPERATIVE ADHESION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOXICITY TO VARIOUS AGENTS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ANGINA UNSTABLE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FIBRILLATION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ATRIAL FLUTTER			

alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CARDIAC FAILURE ACUTE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL INFARCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MYOCARDIAL ISCHAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SICK SINUS SYNDROME			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
CEREBRAL HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
CEREBRAL ISCHAEMIA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CUBITAL TUNNEL SYNDROME			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEADACHE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PARTIAL SEIZURES			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBARACHNOID HAEMORRHAGE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TRANSIENT ISCHAEMIC ATTACK			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VIITH NERVE PARALYSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Blood and lymphatic system disorders			
ANAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
LYMPHADENOPATHY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
VESTIBULAR DISORDER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
ORBITAL OEDEMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
ABDOMINAL ADHESIONS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABDOMINAL PAIN			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 454 (0.66%)	8 / 454 (1.76%)	
occurrences causally related to treatment / all	0 / 3	2 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	

ABDOMINAL DISTENSION				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
COLITIS				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
FLATULENCE				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
DIARRHOEA				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)		
occurrences causally related to treatment / all	0 / 0	1 / 4		
deaths causally related to treatment / all	0 / 0	0 / 0		
GASTROINTESTINAL HAEMORRHAGE				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences causally related to treatment / all	0 / 0	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
GASTRIC ULCER PERFORATION				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 1	0 / 0		
HERNIAL EVENTRATION				
alternative dictionary used: MedDRA 19				

subjects affected / exposed	4 / 454 (0.88%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
INGUINAL HERNIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
ILEUS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
INTESTINAL OBSTRUCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	3 / 454 (0.66%)	3 / 454 (0.66%)	
occurrences causally related to treatment / all	0 / 4	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
LARGE INTESTINAL OBSTRUCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MELAENA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
NAUSEA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

OESOPHAGITIS				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
OESOPHAGEAL PERFORATION				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
PANCREATITIS				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
PANCREATITIS ACUTE				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)		
occurrences causally related to treatment / all	0 / 1	1 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
PANCREATITIS NECROTISING				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences causally related to treatment / all	0 / 1	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
PANCREATITIS RELAPSING				
alternative dictionary used: MedDRA 19				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
RECTAL HAEMORRHAGE				
alternative dictionary used: MedDRA 19				

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 454 (0.44%)	2 / 454 (0.44%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUBILEUS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
VOMITING			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
CHOLELITHIASIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATITIS TOXIC			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATOCELLULAR INJURY			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
JAUNDICE CHOLESTATIC			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
ERYTHEMA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERTROPHIC SCAR			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
RENAL COLIC			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	2 / 454 (0.44%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE ACUTE			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
RENAL FAILURE CHRONIC			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
GOITRE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
TOXIC NODULAR GOITRE			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
ABDOMINAL ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
APPENDICITIS			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
CELLULITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ERYSIPELAS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
GASTROENTERITIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HERPES ZOSTER			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
OTITIS EXTERNA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
PELVIC ABSCESS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

PNEUMONIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
SKIN CANDIDA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
STAPHYLOCOCCAL SEPSIS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
UPPER RESPIRATORY TRACT INFECTION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
DIABETES MELLITUS			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPERGLYCAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOGLYCAEMIA			
alternative dictionary used: MedDRA 19			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPOKALAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
HYPONATRAEMIA			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALNUTRITION			
alternative dictionary used: MedDRA 19			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Observation	Imatinib Mesylate	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	205 / 454 (45.15%)	442 / 454 (97.36%)	
Vascular disorders			
COLD FEET			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLD FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLD HAND			

alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
COLD HAND, FEET			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLD HAND/FEET			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLD HANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	7	
COLD HANDS AND FEET			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ORAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PHLEBITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
POOR CIRCULATION FINGERTIPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	6	
POOR CIRCULATION IN FINGERTIPS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	3		
POOR CIRCULATION OEDEMA alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
RAYNAUD'S LIKE SYNDROME alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
REYNAUD'S LIKE SYNDROME alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
REYNAUD'S-LIKE SYNDROME alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
SENSATION OF HEAVY LEGS alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
SEVERE BRUSING LEFT ARM alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
THROMBOSIS VENA MESENTERICA & PORTA alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
VASCULAR FRAGILITY alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		

VASCULARY WEAKNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VENOUS INSUFFICIENCY IN MEMBERS INFERIORS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
ABDOMEN NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL SCAR CALCIFICATION SURGERY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABDOMINAL WALL RECONSTRUCTION BECAUSE OF LAPAROCELE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ANUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
APPENDECTOMY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BLADDER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

BONE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BRAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BREAST			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BRONCHUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLON			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CONJUNCTIVA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EXCISION OF PAPILLARY CARCINOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EYE NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ILEUM			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
JEJUNOSTOMY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
JOINT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
KIDNEY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
LAPAROTOMY EVENTRATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	5	0	
LIVER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LUNG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MUSCLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NAILS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

NASAL CAVITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NOSE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ORAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
OTHER SURGICAL AND MEDICAL PROCEDURES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PHARYNX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PROSTATE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PLEURA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
RECTUM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
REN SURGERY FOR RENAL CELL CARCINOMA			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SALIVARY GLAND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SINUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SKIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SMALL BOWEL NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
STOMACH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SPLEEN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SURGERY FOR METASTASIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
TEETH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

TENDON			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TONGUE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
THYROID			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRACHEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
UPPER AIRWAY NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URETHRA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
URINARY TRACT NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
UTERUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VAGINA			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
VULVA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
ABDOMEN NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	19 / 454 (4.19%)	46 / 454 (10.13%)	
occurrences (all)	32	100	
AGRESSIVENESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
AGGRESSIVENESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ASTHENIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CHILLS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	12 / 454 (2.64%)	
occurrences (all)	0	31	
CHILLY FEELING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLD FEELING			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	8 / 454 (1.76%)	
occurrences (all)	0	10	
COMMON COLD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	4	
CONJONCTIVAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
DULLED AFTER TAKING DRUG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DUMPING SYNDROM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DUMPING SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	6	
FACE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

FATIGUE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	55 / 454 (12.11%)	272 / 454 (59.91%)	
occurrences (all)	112	1236	
FEELS ASTHENIC, LETHARGIC AFTER TAKING DRUG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FEELS COLD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FEELS HANGOVER AFTER TAKING DRUG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FEVER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	16 / 454 (3.52%)	
occurrences (all)	1	22	
FEVER (OCCASIONAL)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FEVER 38°			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FEVER 39°C			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FLU			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FLU LIKE SYMPTOMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
FLU LIKE SYNDROM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FLU LIKE SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
FLU SYMPTOMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FLU SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FLU-LIKE SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	7 / 454 (1.54%)	
occurrences (all)	0	7	
FLUSHES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)	
occurrences (all)	1	3	
FREEZING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

GAIN WEIGHT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GRIPPAL SYNDROM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HEAD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INSOMNIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	26 / 454 (5.73%)	
occurrences (all)	3	67	
LETHARGY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LOSS OF BODY WEIGHT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MALAISE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MALAISE WITHOUT CONSCIOUSNESS LOSS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MUSCLE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NIGHT SWEAT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
NIGHT SWEATS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
OTHER GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PAIN NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PELVIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
PELVIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	1 / 454 (0.22%)	
occurrences (all)	3	1	
REDUCE PHYSICAL POWER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RENAL TUMOR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

RIGORS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	12	
RIGORS CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RIGORS, CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RIGORS/CHILLS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	8 / 454 (1.76%)	
occurrences (all)	0	23	
SHIVERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	4	
SICKNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SLEEP DISORDER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	3	0	
SLEEP DISTURBANCE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SLEEPING DISORDER			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SWEAT (NIGHT)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SWEAT(NIGHT)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SWEATING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	6 / 454 (1.32%)	
occurrences (all)	6	8	
SWEATS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VITAMIN DEFICIENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
WEAKNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	4	
WEIGHT GAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
WEIGHT GAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	7 / 454 (1.54%)	175 / 454 (38.55%)	
occurrences (all)	10	508	

WIEGHT GAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
Immune system disorders			
ALLERGIC RHINITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ALLERGY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
IODINE ALLERGY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	12	
RHINITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
Reproductive system and breast disorders			
CONISATION ON INTRAEPITHELIAL LESIONS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DYSMENORRHOEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EJACULATORY DYSFUNCTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

ENDOMETRIOSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
ERECTILE DYSFUNCTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	5	
ERECTILE IMPOTENCE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	3	0	
GYNECOMASTIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GYNECOMASTY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYPERMENORRHEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYPERMENORRHOEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYSTERECTOMY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
IMPOTENCE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	2	1	
MENORRHAGIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
MENSES UNREGULARLY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PRIAPISM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
TESTICLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
UNREGULARLY MENSES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URETHRA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
VAGINA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
VAGINAL MUCOSITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

VAGINITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY INSUFICIENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ASTHMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	2	
BILATERAL PULMONARY INFILTRATES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BRONCHITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
BRONCHUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CATARRH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
CHEST/THORAX NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	2 / 454 (0.44%)	
occurrences (all)	2	2	
COLD			

alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
COLD SYMPTOMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COMMON COLD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
COPD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
COUGH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	28 / 454 (6.17%)	
occurrences (all)	4	50	
DEEP VOICES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DYSPHONIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	3	
DYSPNEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	6 / 454 (1.32%)	37 / 454 (8.15%)	
occurrences (all)	9	96	
FEW BASAL CREPS + RONCHI			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
FLU			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HEAD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HOARSE VOICE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
HOARSENESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
INTERSTITIAL PNEUMOPATHY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
LUNG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NASAL CONGESTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NASAL OBSTRUCTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	

ORAL CAVITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PARANASAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
PHARYNGITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PHARYNX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PLEURA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
PNEUMONIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PNEUMONITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PNEUMOPATHY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POLLENOSIS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PULMONARY EMPHYSEME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PULMONITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
RESPIRATORY DISTRESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SINUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SORE THROAT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
THORAX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
THROAT IRRITATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TONSILITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

TRACHEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRACHEITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URTI			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VOICE CHANGES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VOICE CHANGES (HOARSENESS)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
WHEEZING (EXPIRATORY WHEEZING)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
Investigations			
WEIGHT LOSS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	7 / 454 (1.54%)	64 / 454 (14.10%)	
occurrences (all)	9	153	
Cardiac disorders			
ATRIAL FLUTTER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
CARDIAC (GENERAL)			

alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	21 / 454 (4.63%)	38 / 454 (8.37%)	
occurrences (all)	32	79	
PALPITATIONS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PERICADIAL EFFUSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PERICARDIAL EFFUSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
PLEURA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SICK SINUS SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SINUS BRADYCARDIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
Nervous system disorders			
ACOUSTIC NEUROMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
AGITATION			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ANXIETY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	5 / 454 (1.10%)	11 / 454 (2.42%)	
occurrences (all)	6	24	
ARMS : TINGLING/NUMBNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BUTTOCK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BUZZING IN THE EARS (RIGHT)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CARPAL TUNNEL SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
CNS CEREBROVASCULAR ISCHEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COENCENTRATION DIFFICULTY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
COGNITIVE DISTURBANCE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)	
occurrences (all)	3	3	

CONCENTRATION ALTERATION (DIFFICULTY)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	18	
CRAMPS + SMARTING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS LEG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS LOWER LIMB			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
CUBITAL TUNNEL SYNDROM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DECLINED SIGHT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DEPRESSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	6 / 454 (1.32%)	18 / 454 (3.96%)	
occurrences (all)	13	39	
DIFFICULTY WITH SHORT TERM MEMORY			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DIZZINES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
DIZZINESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	3 / 454 (0.66%)	32 / 454 (7.05%)	
occurrences (all)	5	57	
DIZZY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DIZZY SPELL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DIZZYNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EYE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FACIAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	10	
FAINTING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

FORGETFULNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HEAD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INSOMNIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	8	
IRASCIBLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LACK OF CONCENTRATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEFT LIMB PARESTHESIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEG CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MEMORY IMPAIRMENT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	1	2	
MEMORY INPAIRMENT			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MIGRAINES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MOOD ALTERATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	4 / 454 (0.88%)	
occurrences (all)	1	6	
MUSCLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	8	
MOOD ALTERATION-DEPRSSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NEUROPATHY CRAMP HANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NEUROPATHY SENSORY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	5	
NECK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
NEUROPATHY- SENSORY (FORMICATION IN HANDS)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

NEUROPATHY: CRAMP HANDS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	8		
NEUROPATHY: CRANIAL - CN I SMELL				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NEUROPATHY: CRANIAL : CN V				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NEUROPATHY: CRANIAL -CN I SMELL				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NEUROPATHY: CRANIAL: CN V				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NEUROPATHY:SENSORY (PARAESTHESIAS)				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NEUROPATHY-SENSORY				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences (all)	0	2		
NEUROPATHY-SENSORY (PARESTHESIA HANDS)				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NUMB FINGERS				

alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NUMBNESS OF LEFT THIGH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
NUMBNESS AROUND OPERATION SITE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NUMBNESS-COLATERAL HAND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OBNUBILATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	5	
OTH DISC DEGENERATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PARAESTHESIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PARASHESIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PARASTHESIA			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	5	
PARASTHESIAS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PARESTHESIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
PARESTHESIAS ON HANDS AND FEET			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PARESTHESIE FOOT BILATERAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PERIPHERAL POLYNEURITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PINS+NEEDLE SENSATION DOWN LEG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POOR CIRCULATION FINGER TIPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
POLYNEUROPATHY			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POOR CONCENTRATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POOR CONCENTRATION (ADD)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
R SCIATICA NERVE PAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SEIZURE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
SENSITIVE DYESHESIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SENSORY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SENSORY NEUROPATHY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SENSORY NEUROPATHY (HANDS)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	

SENSORY NEUROPHATY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SEVERE NUMBNESS LEFT FOOT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SENSORY: LEFT UPPER LEG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SMARTING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
SLUMBER TROUBLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
SMELL LOSS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SOMNOLENCE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
STIFFNESS FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
SYNCOPE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
TINGLING FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
TINGLING LEFT ARM + FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRANSISCHEMIC ATTACK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TREMOR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	10	
TRENSION OF UPPER EXTREMITIES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
TWO LYPOTHYMIC EPISODES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VAGAL DISCONFORT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VERTIGO			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	4 / 454 (0.88%)	
occurrences (all)	1	18	

WEEKNESS RIGHT LEG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
ABDOMINAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	5	
ANEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	6 / 454 (1.32%)	
occurrences (all)	1	17	
ANKLE SLIGHTY SWOLLEN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BLOCKED RIGHT EAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
EDEMA FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EDEMA LEGS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EDEMA VISCERA			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	7 / 454 (1.54%)	
occurrences (all)	0	11	
EDEMA, HEAD&NECK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	4 / 454 (0.88%)	284 / 454 (62.56%)	
occurrences (all)	8	1555	
EDEMA, LIMBS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	3 / 454 (0.66%)	127 / 454 (27.97%)	
occurrences (all)	3	386	
EDEMA, TRUNK/GENITAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	6	
EOSINOPHILIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
EXCESSIVE LACRIMATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
EYE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	3	
HEMATOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	5 / 454 (1.10%)	
occurrences (all)	2	7	
HEMOGLOBIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

IRON DEFICIENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
LEGS VENOUS FAILURE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LYMPH NODE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MESENTERIC PANNICULITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
NEUTROPENIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OEDEMA BUT LOCATION NOT RECORDED			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PALPABLE LYMPHNODE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PALPABLE LYMPHNODE SUBMANDIBULAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
RIGHT KNEE SWOLLEN			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SIDEROPENIC ANAEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SWOLLEN GLAND (SUBMANDIBULAR)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SWOLLEN GLANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
UNSPECIFIED OEDEMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
WATER RETENTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
Ear and labyrinth disorders			
AUDITORY/EAR -> BLOCKED EARS WITH MAX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DEAFNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
EAR NOISES			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HEARING (ACOUSTIC PROBLEMS)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYPOACUSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEFT EAR RINGING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OTITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
TINNITUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	6	
VESTIBULAR FAILURE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
Eye disorders			
ALLERGICAL CONJUNCTIVITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BLEPHARITIS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BLURRED VISION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	7 / 454 (1.54%)	
occurrences (all)	1	11	
BURN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CATARACT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CONJONCTIVITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	5	
CONJUNCTIVA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CONJUNCTIVITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	7 / 454 (1.54%)	
occurrences (all)	0	23	
DECREASE OF VISUAL FUNCTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DECREASE VISUAL FUNCTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

DIPLOPIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
DRY EYE SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	6	
DRY MUCOUS MEMBRANE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DRY MUCUOUS MEMBRANE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EYE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	22 / 454 (4.85%)	
occurrences (all)	0	34	
GLAUCOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
HYPEREMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
IMPAIRED VISION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ITCHING PERIORBITAL			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
LACRIMATION INCREASED			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
MACULAR DEGENERATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
NYSTAGMUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OCULAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OCULAR SURFACE DISEASE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	18 / 454 (3.96%)	
occurrences (all)	0	33	
OPHTALMIC TROUBLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PHOTOPHOBIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TEARING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	6	

TEARING (+COPING PROBLEMS) alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VISION DISTURB alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VISUAL DISTURBANCE alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VISUAL TROUBLE alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
WATERY EYE alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	26 / 454 (5.73%)	
occurrences (all)	1	84	
Gastrointestinal disorders			
ABDO PART, BLOATING alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABDOMEN alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	20 / 454 (4.41%)	29 / 454 (6.39%)	
occurrences (all)	38	48	
ABDOMEN NOS alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ABDOMINAL alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	18 / 454 (3.96%)	37 / 454 (8.15%)	
occurrences (all)	29	65	
ABDOMINAL BLOATING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	1	2	
ABDOMINAL COLIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ABDOMINAL COLICS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABDOMINAL CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABDOMINAL CRAMPING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABDOMINAL CRAMPING AFTER INTAKE OF IMATINIB			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABDOMINAL CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)	
occurrences (all)	2	3	
ABDOMINAL DISCONFORT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	3	

ABDOMINAL DISTENSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
ABDOMINAL FULLNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL HERNIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
ABDOMINAL HERNIA OF THE SCAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ABDOMINAL HERNIA SCAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
ABDOMINAL MASS STITCH ABCESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABDOMINAL SCAR HERNIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
ABDOMINAL SENSITIVE TOUCH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ACID REFLUX			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ACID REGURGITATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
ACIDITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
ACUTE GASTROENTERITIS WITH AUTOLIMITED RECTAL BLEEDING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ADDED DEJECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ADENOMA OF THE SIGMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ADHESIONS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ANAL MUCOSITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ANUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	

APHTOSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ASCITES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
BELCHING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	6	
BLACK STOOL (2X)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BLACK STOOLS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BLOATED FEELING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BLOATED FEELINGS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BLOATING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)	
occurrences (all)	1	4	
BLOATING AND INDIGESTION			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BORBORYGMUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BOWEL ADHESION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BOWEL COMPLAINTS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
BOWEL OBSTRUCTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BUCCAL MUCOSITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BURN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
CHOLELITHIASIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLIC POLYPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

COLITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COLON			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CONSIPATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CONSITPATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CONSTIPATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	18 / 454 (3.96%)	45 / 454 (9.91%)	
occurrences (all)	30	110	
COPROSTASE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
COPROSTASIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DEFAECATION NOT REGULAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DEHYDRATATION			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DENTAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DENTAL/TEETH/PERIDONTAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
DIARRHEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	41 / 454 (9.03%)	219 / 454 (48.24%)	
occurrences (all)	76	874	
DIFFICULTY OF SWALLOWING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DIFFICULTY SWALLOWING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DIGESTIVE DISORDER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DISCONFORT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DISGUEUSIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

DISPESIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DISTENSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	4 / 454 (0.88%)	3 / 454 (0.66%)	
occurrences (all)	4	3	
DISTENSION/BLOATING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	0 / 454 (0.00%)	
occurrences (all)	3	0	
DISTENSION/BLOATING, ABDOMINAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DISTENSTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DISTENTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DRY MONTH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DRY MOUNTH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
DRY MOUTH			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	13 / 454 (2.86%)	
occurrences (all)	0	29	
DRY THROAT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DUMPING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DUMPING SYNDROM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DUMPING SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DYSFAGIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DYSGEUSIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DYSPEPSIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	4 / 454 (0.88%)	12 / 454 (2.64%)	
occurrences (all)	4	19	
DYSPESIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	

DYSPHAGIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	7 / 454 (1.54%)	
occurrences (all)	1	11	
DYSPHAGY (ANASTOMOSE)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EARLU SATIETY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EARLY SATIETY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	3 / 454 (0.66%)	
occurrences (all)	3	7	
ENTERITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
EPIDGASTRIC HEAVINESSES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EPIGASTRALGIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	10 / 454 (2.20%)	
occurrences (all)	0	19	
EPIGASTRALGY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
EPIGASTRIC BLOATING			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
EPIGASTRIC DISCOMFORT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	2 / 454 (0.44%)	
occurrences (all)	2	2	
EPIGASTRIC DISCONFORT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EPIGASTRIC TENDERNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
EPYGASTRALGY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ERUCTATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	4	3	
ESOPHAGEAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ESOPHAGITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	7 / 454 (1.54%)	
occurrences (all)	1	16	
FAECAL PAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	

FEELING BLOATED			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
FEELING OF FULLNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
FISTULA COLO-CUTANEOUS PRESACRUM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
FISTULA COLO-CUTANEOUS PRE-SACRUM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	3	0	
FLATULENCE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	10 / 454 (2.20%)	12 / 454 (2.64%)	
occurrences (all)	12	29	
FUSTULA IN THE ANASTOMOSUS OESOPHAGA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FUSTULA OF OESOPHAGEAL-JEJUNAL ANAST			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GALLSTONES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
GASTR- OESOPHAGEAL REFLUX			

alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTRALGIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	10	
GASTRIC ACIDITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	4	
GASTRIC DISCOMFORT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTRIC DISCONFORT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTRIC REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	4 / 454 (0.88%)	
occurrences (all)	1	4	
GASTRIC TROUBLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
GASTRITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	4 / 454 (0.88%)	10 / 454 (2.20%)	
occurrences (all)	4	15	
GASTRO ENTERITIS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTRO ESOPHAGEAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTRO ESOPHAGIAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTRO OESOPHAGEAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTROENTERITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	7 / 454 (1.54%)	
occurrences (all)	0	7	
GASTRO-ENTERITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTROENTRETIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTROESOPHOGAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GASTRO-INTESTINAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

GASTRO-OESOPHAGAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
GERD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	4	0	
GRAVITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
GRELIC OCCLUSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GUT CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
HEARTBURN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	10 / 454 (2.20%)	29 / 454 (6.39%)	
occurrences (all)	12	58	
HEARTBURN/DYSPEPSIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
HEMORRHOIDAL CONGESTION WITH UNCONTROLLED PAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HEMORRHOIDS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	2 / 454 (0.44%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
HERNIE SCAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
HIATAL HERNIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	14	
ILEUM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ILEUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ILEUS (ADHESION)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INCISIONAL HERNIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INCREASE BELCHING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INCREASE OF APETITE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	

INCREASED ABDOMINAL HERNIA SCAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
INCREASED APETITE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
INCREASED BOWEL OPENING 6-8 TIMES DAILY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INDIGESTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	8 / 454 (1.76%)	
occurrences (all)	3	10	
INTERMITTENT GASTRIC REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INTESTINAL SUBOCCLUSION CRISIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INTESTINAL TRANSIT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INTOLERANCE ON FATTY FOODS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
IRREGULAR DEFECATION			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LACK OF APETITE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LEFT RECTUS ABDOMINIS NODULE ABLATION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LOSS OF APETITE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LOSS OF APPETITE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences (all)	0	2		
MALNUTRITION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
MELAENA				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
METEORISM				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)		
occurrences (all)	0	4		
METEORISMUS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	2 / 454 (0.44%)	1 / 454 (0.22%)		
occurrences (all)	2	1		

MOUTH ULCER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MUCOSA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MUCOSITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	8 / 454 (1.76%)	
occurrences (all)	1	20	
MUSHY DEFECATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
NAUSEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	25 / 454 (5.51%)	198 / 454 (43.61%)	
occurrences (all)	33	675	
OBSTIPATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	3 / 454 (0.66%)	5 / 454 (1.10%)	
occurrences (all)	4	6	
OESOPHAGEAL REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ORAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ORAL CAVITY			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PANCREATITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	1	2	
PASSAGE PROBLEMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PERIANAL WARMTH POST GLIVEC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PHARYNX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PIROSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POST PANDRIAL FULLNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
POOR APPETITE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POSTPANDRIAL HEAVINESS AFTER TO TAKE IMATINIB			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

POUTH DRYNESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PRESSURE EPIGASTRIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PRESURE EPIGASTRIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PYROSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	10 / 454 (2.20%)	
occurrences (all)	3	21	
RCU			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RECTAL BLEEDING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
RECTAL INCONTINENCE (OCCASSIONAL)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
RECTUM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	2	
RECTAL TENESMUS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	4	
REFLUX (OCCASIONAL)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
REFLUX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	5 / 454 (1.10%)	
occurrences (all)	4	9	
REFLUX GASTROOESOPHAGEAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RGO			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	8	
REGURGITATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
RUCTUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	2 / 454 (0.44%)	
occurrences (all)	3	6	
SALIVARY GLAND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SLIGHT DYSPHAGY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

SMALL BLISTER MOUTH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SMALL BOWEL NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SMALL HERNIA UMBILICALIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SORETHROAT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
STOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	4 / 454 (0.88%)	
occurrences (all)	1	5	
SUBILEUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
STOMACH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	4 / 454 (0.88%)	19 / 454 (4.19%)	
occurrences (all)	6	34	
TASTE ALTERATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	29 / 454 (6.39%)	
occurrences (all)	0	68	
SUSPECTED GIST RECURRENCE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SUBOCCLUSION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
TEETH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
THIRST			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
THIRSTY SENSATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	6	
TONGUE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	6	
TOOTH DECAY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRACHEA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRANSIT-INTESTINAL GESTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	

ULCER OESPHAGUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VESICAL MUCOSITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VOMITING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	14 / 454 (3.08%)	89 / 454 (19.60%)	
occurrences (all)	16	138	
Hepatobiliary disorders			
BILIARY COLI			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HEPATIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LIVER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PANCREATITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TOXIC HEPATITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	5	
Skin and subcutaneous tissue disorders			

ACNE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	3	
ALOPECIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	31 / 454 (6.83%)	
occurrences (all)	2	60	
AURICULAR ECZEMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BACK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BASOCELLULAR EPITHELIOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BLISTER RIGHT ARM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BRUISING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
BUCCAL RHAGADES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BURN			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences (all)	0	3		
CHANGE IN HAIR COLOR				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CHEILITIS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	2		
CHELITIS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CONTACT DERMATITIS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CONTACT DERMATITIS ON HANDS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CUT RIGHT HAND				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CUTANEOUS DRYNESS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	6 / 454 (1.32%)		
occurrences (all)	0	6		
CUTANEOUS ERRUPTION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		

CUTANEOUS ERUPTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
CUTANEOUS REACTION TO IODE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DEPIGMENTATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DERMATITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DISCOMFORT FROM SCAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DRY HANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DRY LEGS+FEET/ATHLETES FOOT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
DRY SKIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	4 / 454 (0.88%)	32 / 454 (7.05%)	
occurrences (all)	4	65	
DRY SKYN			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	4	
DYSCHROMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ECZEMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	6 / 454 (1.32%)	
occurrences (all)	0	14	
ECZEMA (ARMS/TOUTH)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ECZEMA (LOWER LIMBS)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ECZEMA ON HAND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ECZEMA RIGHT HAND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ERYSIPELAS LEFT LEG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ERYSIPELOID LESION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

ERYTHEMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	8 / 454 (1.76%)	
occurrences (all)	1	23	
ERYTHEMA FINGERS HANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ERYTHEMA LESION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ERYTHEMA ON THE HANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ERYTHEMA PERIORBITAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ERYTHEMA WITH HYPERKERATOSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	5	
EXANTHEMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	5	
EXCOLIATION BELOW KNEE BOTH LEGS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EYE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)	
occurrences (all)	0	12	
FACE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	12	
FACIAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FLUCHES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
FLUSHING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	3	3	
FOLLICLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FOLLICULITE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	4	
FOLLICULITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FUNGAL RASH ON LEGS AND ARMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	

HAIR LOSS/ALOPECIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND +FOOT SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND REACTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND-FOOT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HANDS ECZEMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HERPES SIMPLEX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYPERPIGMENTATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	6	
HYPOPIGMENTATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)	
occurrences (all)	0	15	
INFECTED INSECT BITE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
INFLAMED UMBILICUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ITCHING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)	
occurrences (all)	0	11	
ITCHING BOTH ARMS AND LEGS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ITCHING RIGHT KNEE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
KERATOSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
L ANKLE MACULOPAPULAR MARK IMPROVING			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LASH AND BROW LOSS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LASH LOSS, BROW LOSS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	

LAT. UPPER L LEG ERYTEMA SCALY PLAQU			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LESION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LIP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	5	
MACULAR LESION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MACULOPAPULAR MASK ABOVE L ANKLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MULTIPLE KERATOACANTHOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NAEVUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NAIL CHANGES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	3	
NAIL LOSS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NAILS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
NOT SPECIFIED			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	2	1	
OCULAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ONYCHORRHEXIS (UNGUEAL TOXICITY)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OTH DERMATITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PAPILLOMATOUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
PERIORBITAL ERYTHEMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PHOTOSENSITIVITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

PRURIT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
PRURITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	13 / 454 (2.86%)	
occurrences (all)	1	25	
PRURITIS LEGS AND ARMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PRURITUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	14 / 454 (3.08%)	
occurrences (all)	2	37	
PRUTITUS (INTERMITTENT PRURIT)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PSIORASIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PSIORIASIS VULGARIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PSORIASIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)	
occurrences (all)	3	7	
PSORIASIS LIKE LESIONS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
PSORIASIS-LIKE LESIONS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PURITIS MEDIAL LEFT CALF			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RASH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
RASH (AXILLARY)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RASH RIGHT LEG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RECURRENT LESIONS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RIGORS/CHILLS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RING WORM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

SCALP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	1	2	
SCAR HERNIATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SEBORRHEIC KERATOSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SEBORRHEIC WART ERUPTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
SKALP KIST			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SKIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	12 / 454 (2.64%)	
occurrences (all)	0	14	
SUN SENSITIVITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SWELLING & THICKENING SUBCUTAN TISS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SWELLING THICKENING OF SUBCUTAN TISS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SWELLING&THICKENING OF SUBCUT. TISSU			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TELANGIECTASIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRUNK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ULCERATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ULCER-POSSIBLE SPIDER BITE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
UNGUEAL TOXICITY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
WATER BLISTER (LOWER LEFT LEG)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
WOUND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	

Renal and urinary disorders			
BLADDER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	12	
CHRONIC RENAL INSUFFICIENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
CHRONIC RENAL INSUFICIENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
COLITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CREATININ CLEARANCE DECREASE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CYSTITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	6	
DISURIA (URINARY PAIN)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DYSURIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	4	
FIBROID UTERINE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
HEMATURIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYDROCAELE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INCREASE OF PSA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
KIDNEY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
LOW URINE OUTPUT (LOW VOLUME)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LOWERING OF CREATININ CLEARANCE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OFFENSIVE SMELLING URINE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PELVIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	

PERSITENT PV DISCHARGE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POLLAKIURIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PROSTATE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PROSTATIC HYPERTROPHY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
PROSTATITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RENAL CHRONIC FAILURE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RENAL COLIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	4	
RENAL FAILURE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RENAL INSUFFICIENCY			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
STOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URETHRA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
URINARY DIFFICULTY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
URINARY FREQUENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	4 / 454 (0.88%)	
occurrences (all)	1	7	
URINARY FREQUENCY (NOCTURIA)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URINARY INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URINARY TRACT SYMPTOMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
UTERUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

VAGINA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
DIABETES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
DIABETES (SURGERY RELATED)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
FLUSHES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	1 / 454 (0.22%)	
occurrences (all)	2	2	
HOT FLASHES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)	
occurrences (all)	0	14	
HYPERTHYROIDISM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
THYROID			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	4	
Musculoskeletal and connective tissue disorders			
ABDOMEN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
ANKYLOSIS MAXILLA			

alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
ARTHRITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	5	2	
ARTHROSES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
ARTHROSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	2 / 454 (0.44%)	0 / 454 (0.00%)	
occurrences (all)	10	0	
BURSITIS SHOULDER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
BUTTOCK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
CALF CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
CALFS CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CERVICAL CONTRACTURE			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	9	
CRAMP (HANDS)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMP IN FEET AND FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMP IN FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMP IN THE CALF			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMP LEGS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMP ON BOTH FEET			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPING LEGS (CA2+/MG ADVISED BY GP)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	

CRAMPING LEGS/HANDS NOW AND THEN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	15 / 454 (3.30%)	
occurrences (all)	0	41	
CRAMPS CALVES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS DURING THE NIGHT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	5	
CRAMPS FINGERS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS HAND AND FOOT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS HANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS IN CALVES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS IN HANDS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CRAMPS IN HANDS AND LEG				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CRAMPS IN HANDS/LEGS/FEET				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CRAMPS IN LEGS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CRAMPS IN THE HAND				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	2		
CRAMPS IN THE LEGS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CRAMPS LEFT THUMB				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	3		
CRAMPS LEG/ARM				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
CRAMPS LEGS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences (all)	0	3		

CRAMPS RIGHT TOE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS RIGHT TOES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMPS-RIGHT TOES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CRAMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EXTREMITY-LIMB			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	4 / 454 (0.88%)	9 / 454 (1.98%)	
occurrences (all)	4	14	
FACIAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
FALLEN ARCHES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	10	
FALLEN ARCHES (BOTH FEET)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FALLEN ARCHES BOTH FEET			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
FALLEN ARCHES FEET				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	2		
FALLEN ARCHES -FEET				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
FALLEN ARCHES IN FEET				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	2		
FALLEN ARCHES-FEET				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
FEET NOCTURNE CRAMPS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
FRACTURE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)		
occurrences (all)	1	4		
GENERALISED CRAMPS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
GOUT				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	2 / 454 (0.44%)	2 / 454 (0.44%)		
occurrences (all)	2	2		

GOUT (R. FOOT)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GOUT L GREAT TOE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND AND LEG CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
HANDS AND CALF CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HANDS AND LEGS CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HANDS AND LEGS CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND'S CRAMP			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HANDS CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
HEAD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INGUEN HERNA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INTERMITTANT CRAMPS IN THE HANDS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
L FOOT CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
L THUMB CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
L THUMB CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEG CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	

LEG CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)	
occurrences (all)	0	9	
LEG CRAMPS (MILD)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEG/ARM CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEG/ARM CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEGS AND HANDS CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
LEGS CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LUMBAGO			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
MASCULAR CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
-MUS WEAKNESS EXTREMITY LOWER			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
MUSCLE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	54 / 454 (11.89%)		
occurrences (all)	1	122		
MUSCULAR CRAMPS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences (all)	0	7		
MUSLE SPASMS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NECK				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	2 / 454 (0.44%)	1 / 454 (0.22%)		
occurrences (all)	2	1		
NIGHT CRAMPS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences (all)	0	2		
NOCTURAL CRAMPS (FEET+CALVES)				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
NUMBNESS IN KNEE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	2		
NUMBNESS IN L KNEE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		

OCULAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OSTEOPOROSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	1	
PELVIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PLANTAR FASCIITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
R FOOT CRAMP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	4	
R FOOT CRAMPS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RIGHT FOOT GOUT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SUBARCROMIAL IMPINGEMENT SYNDROME			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TENDON			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	5	
TENDOPATHY THIGH NIGHT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
THORAX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRISMUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TRUNK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
Infections and infestations			
ABDOMEN NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ABSCESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	4	
AIRWAY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ATHLETE'S FOOT			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ANGINA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
BLADDER (URINARY)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BONE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BORRELIOSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
BRAIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BRONCHITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	7 / 454 (1.54%)	
occurrences (all)	0	7	
BRONCHITIS (5 DAYS)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
BRONCHITIS (NORMAL ANC)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	

BRONCHUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)	
occurrences (all)	0	6	
CELLULITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CELLULITIS, LEFT LEG			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CHEST INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
COLD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)	
occurrences (all)	1	3	
COLD SORES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
COLON			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
COMMON COLD WITH FEVER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CONJUNCTIVA			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	1	2	
CONJUNCTIVITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	5	
CYSTISIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CYSTITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	8	
DENTAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
DENTAL-TOOTH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
DIVERTICULITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EAR INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
ESOPHAGITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	

EXTERNAL EAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
EYE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	3	
EYE NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FEBRILE NEUTROPENIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	5	
FEVER BUTTON			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FEVER DUE TO SWOLLEN GUMS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
FISTULA WITH ABCESS IN BURSA OMENTALIS MESENTERIAL PANNICULITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
FLU			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
FLU LIKE ILLNESS			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
GASTRIC ABCESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GENITAL CONDYLOMA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
GRIPPAL SYNDROM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HAND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HEAD			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	4	
HELICOBACTER PYLORI			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
HELICOBECTER PYLORI			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
HEPATITIS B			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

HERPES SIMPLEX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
HERPES VIRUS INFECTION (SHINGLES)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
HERPES ZOSTER			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	1	2	
HERPES ZOSTER VIRUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
ILEUM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
INF GASTRIC MOCOSA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INF GASTROENTERITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)	
occurrences (all)	0	4	
INF GASTROINTESTINAL INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
INF GASTRO-INTESTINAL INFECTION			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
INF PULMONARY SEPSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INF PULMONARY/UPPER RESPIRATORY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INFECTED PIMPLE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
INFECTED RIGHT EAR			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INFECTED SEBACEOUS CYST			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INFECTION ACNE OUTBREAK			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INFECTION IN ORL SPHERE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
INFECTION WITH UKNOWN ANC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

INFLUENZA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)	
occurrences (all)	0	5	
INFLUENZAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
JOINT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
KIDNEY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LARYNGITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
LEFT EAR INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LEFT SIDE NECROTISING OTITIS LEFT EXTERNA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LIP			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
LIVER			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LOWER RESPIRATORY INFECTION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LOWER RESPIRATORY TRACT INFECTION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LUMP FLUID R ARMPIT WITH PURULENT				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LUNG				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
LUNG (PNEUMONIA)				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
MRSA RESISTENT SEPSIS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
MUCOSA				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
MUSCLE				
alternative dictionary used: CTCAE 3.0				

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
MYCOSIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NAILS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
NOSE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OTH ACUTE GASTROENTERITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OTITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
PARANASAL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PELVIC			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PELVIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	

PHARINGYTIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PHARYNGITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PHARYNX			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PNEUMATIC/BRONCHITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
PNEUMONIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	3	
PNEUMONIA (VIRAL INFECTION)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
POSSIBLE RINGWORM			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PROSTATE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RECTUM			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
RESPIRATORY INFECTION WITHOUT NEUTROPENI			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RHINITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
RHINO-PHARINGITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
RHINOPHARYNGITIS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
RIGHT FOOT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SALIVARY GLAND			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SEASONAL INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
SHINGLES			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

SINUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
SKIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	2	
SMALL BOWEL NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
SPLEEN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
STITCH ABSCESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
STOMACH			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
TOOTH ABCESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TOOTH ABSCESS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
TOOTH INFECTION			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
TOOTH SHAM				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
TRACHEA				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
UNGUEAL INFECTION N/A LEVURE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
UPPER AIRWAY NOS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)		
occurrences (all)	0	5		
UPPER RESPIRATORY				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
UPPER RESPIRATORY INFECTION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
UPPER RESPIRATORY TRACT INFECTION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)		
occurrences (all)	1	3		
URETHRA				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		

URINARY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URINARY INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	3	
URINARY TRACT INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)	
occurrences (all)	1	2	
URINARY TRACT NOS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
URINE INFECTION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
UTERUS			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VAGINA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VEIN			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
VIRAL			
alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
VIRAL ILLNESS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
VIRAL INFECTION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)		
occurrences (all)	1	1		
VIRAL INFECTION (COMMON COLD VIRUS)				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	3		
VIROLOFICAL HERPES ZOSTER				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
VIRUS				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	2		
VIRUS INFECTION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
VULVA				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
WOUND				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)		
occurrences (all)	0	4		

ZONA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
ALAT=40N, ASAT=20N (HEPATO TOXICITY)			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ALT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ALT, AST			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
ANOREXIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	16 / 454 (3.52%)	55 / 454 (12.11%)	
occurrences (all)	27	121	
BILIRUBIN INCREASE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
BILIRUBIN-INCREASE			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CHOLESTEROL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
CPK			
alternative dictionary used: CTCAE			

3.0				
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)		
occurrences (all)	0	6		
CREATININE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)		
occurrences (all)	0	4		
DEFICIENCY FE, FOLIC ACID,VIT B12				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
DEHYDRATION				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
GGT (82U/L)				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)		
occurrences (all)	1	0		
GGT INCREASE				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	3		
HEPATIC				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
HYPERBILIRUBINEMIA				
alternative dictionary used: CTCAE 3.0				
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)		
occurrences (all)	0	1		
HYPERCHOLESTREMIA				
alternative dictionary used: CTCAE 3.0				

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYPERGLYCEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	3 / 454 (0.66%)	
occurrences (all)	1	10	
HYPERURICEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	3	
HYPOCALCEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYPOGLYCEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	4	
HYPOKALEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)	
occurrences (all)	0	9	
HYPONATREMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
HYPOPHOSPHATEMIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	6	
INCREASE GGT			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

IRON DEFICIENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
METRORRHAGIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OTH DEFICIT OF VIT B12			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
OTH IRON DEFICIENCY			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	2	0	
OTH UREA = 61 MG/DL [17-43]			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
PROTEINURIA			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)	
occurrences (all)	1	9	
RAISED CHOLESTEROL			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
TSH ELEVATION			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 March 2009	In March 2009, the overall survival was estimated in the control group, to investigate whether the assumptions supporting the statistical design were verified; it became clear that the planned interim analysis of survival would not be possible before the question had lost its interest, due to a substantially better than expected survival in the control group. The IDMC strongly recommended an amendment of the protocol to change the primary end-point to time to imatinib failure.
13 December 2011	The IDMC recommended a further amendment of the protocol to change the definition of primary end-point to 'imatinib monotherapy failure free survival'. This definition was thought to be simple, pragmatic, objective, and easier to understand than the previous definition.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported