



## 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
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#### 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:

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**Subjects enrolled per age group**

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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

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## 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
<b>Arm title</b>	Observation

Arm description:

Follow-up after surgery without further antitumoral therapy

Arm type	No intervention
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No investigational medicinal product assigned in this arm

<b>Arm title</b>	Imatinib mesylate
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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

<b>Number of subjects in period 1</b>	Observation	Imatinib mesylate
Started	454	454
Completed	454	454

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**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
<b>Arm title</b>	Observation

Arm description:

Follow-up after surgery without further antitumoral therapy

Arm type	No intervention
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No investigational medicinal product assigned in this arm

<b>Arm title</b>	Imatinib mesylate
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Arm description:

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

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

400mg/day during 2 years

<b>Number of subjects in period 2</b>	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		

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

## Statistical analyses

<b>Statistical analysis title</b>	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 <sup>[1]</sup>
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)

<b>Statistical analysis title</b>	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	

<b>End point values</b>	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		

<b>Attachments (see zip file)</b>	RFS - Adjusted/RFS.png
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### Statistical analyses

<b>Statistical analysis title</b>	Relapse 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

<b>Statistical analysis title</b>	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		

<b>Attachments (see zip file)</b>	OS - adjusted/OS adj.png
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### Statistical analyses

<b>Statistical analysis title</b>	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

<b>Statistical analysis title</b>	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
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19
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### Reporting groups

Reporting group title	Observation
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Reporting group description:

Observation

Reporting group title	Imatinib Mesylate
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Reporting group description:

Imatinib Mesylate

<b>Serious adverse events</b>	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	
<b>BREAST CANCER</b>			
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	
<b>BRONCHIAL CARCINOMA</b>			
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	
<b>CHRONIC LYMPHOCYTIC LEUKAEMIA STAGE 0</b>			
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	
<b>DESMOID TUMOUR</b>			
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	
<b>ENDOMETRIAL ADENOCARCINOMA</b>			
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	
<b>GASTROINTESTINAL STROMAL TUMOUR</b>			
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	
<b>RENAL CANCER</b>			
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	
<b>RENAL CELL CARCINOMA</b>			
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	
<b>SCHWANNOMA</b>			
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	
<b>SQUAMOUS CELL CARCINOMA</b>			
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	
<b>TUMOUR HAEMORRHAGE</b>			
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	
<b>UTERINE LEIOMYOMA</b>			
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	
<b>General disorders and administration site conditions</b>			
<b>CHEST PAIN</b>			
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	
<b>DISEASE RECURRENCE</b>			
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	
<b>FATIGUE</b>			
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	
<b>GENERAL PHYSICAL HEALTH DETERIORATION</b>			
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	
<b>MULTI-ORGAN FAILURE</b>			
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	
<b>NODULE</b>			
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	
<b>OEDEMA PERIPHERAL</b>			
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	
<b>PYREXIA</b>			
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	
<b>Reproductive system and breast disorders</b>			
<b>ENDOMETRIOSIS</b>			
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	
<b>GENITAL HAEMORRHAGE</b>			
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	
<b>VAGINAL PROLAPSE</b>			
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	
<b>Respiratory, thoracic and mediastinal disorders</b>			
<b>ACUTE RESPIRATORY FAILURE</b>			
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	
<b>DYSпноEA</b>			
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	
<b>LUNG DISORDER</b>			
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	
<b>PLEURAL EFFUSION</b>			
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	
<b>PNEUMONITIS</b>			
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	
<b>PULMONARY EMBOLISM</b>			
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	
<b>PULMONARY FIBROSIS</b>			
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 occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 454 (0.22%) 0 / 1 0 / 0	1 / 454 (0.22%) 0 / 1 0 / 0	
Psychiatric disorders DEPRESSED MOOD alternative dictionary used: MedDRA 19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 454 (0.00%) 0 / 0 0 / 0	1 / 454 (0.22%) 0 / 1 0 / 0	
DEPRESSION alternative dictionary used: MedDRA 19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 454 (0.22%) 0 / 1 0 / 0	1 / 454 (0.22%) 1 / 1 0 / 0	
MAJOR DEPRESSION alternative dictionary used: MedDRA 19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	1 / 454 (0.22%) 0 / 1 0 / 0	0 / 454 (0.00%) 0 / 0 0 / 0	
Investigations ALANINE AMINOTRANSFERASE INCREASED alternative dictionary used: MedDRA 19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 454 (0.00%) 0 / 0 0 / 0	1 / 454 (0.22%) 1 / 1 0 / 0	
ASPARTATE AMINOTRANSFERASE INCREASED alternative dictionary used: MedDRA 19 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 454 (0.00%) 0 / 0 0 / 0	1 / 454 (0.22%) 1 / 1 0 / 0	
OESOPHAGOGASTRODUODENOSCOPI			

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	
<b>CARDIAC FAILURE ACUTE</b>			
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	
<b>MYOCARDIAL INFARCTION</b>			
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	
<b>MYOCARDIAL ISCHAEMIA</b>			
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	
<b>SICK SINUS SYNDROME</b>			
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	
<b>Nervous system disorders</b>			
<b>CEREBRAL HAEMORRHAGE</b>			
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	
<b>CEREBRAL ISCHAEMIA</b>			
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	
<b>CUBITAL TUNNEL SYNDROME</b>			
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	
<b>HEADACHE</b>			
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	
<b>PARTIAL SEIZURES</b>			
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	
<b>SUBARACHNOID HAEMORRHAGE</b>			
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	
<b>TRANSIENT ISCHAEMIC ATTACK</b>			
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	
<b>VIITH NERVE PARALYSIS</b>			
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
<b>INGUINAL HERNIA</b>		
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
<b>ILEUS</b>		
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
<b>INTESTINAL OBSTRUCTION</b>		
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
<b>LARGE INTESTINAL OBSTRUCTION</b>		
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
<b>MELAENA</b>		
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
<b>NAUSEA</b>		
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	
<b>SMALL INTESTINAL OBSTRUCTION</b>			
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	
<b>SUBILEUS</b>			
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	
<b>VOMITING</b>			
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	
<b>Hepatobiliary disorders</b>			
<b>CHOLECYSTITIS</b>			
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	
<b>CHOLELITHIASIS</b>			
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	
<b>HEPATITIS TOXIC</b>			
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	
<b>HEPATOCELLULAR INJURY</b>			
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	
<b>JAUNDICE CHOLESTATIC</b>			
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	
<b>Skin and subcutaneous tissue disorders</b>			
<b>ERYTHEMA</b>			
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	
<b>HYPERTROPHIC SCAR</b>			
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	
<b>Renal and urinary disorders</b>			
<b>RENAL COLIC</b>			
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	
<b>RENAL FAILURE ACUTE</b>			
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	
<b>RENAL FAILURE CHRONIC</b>			
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	
<b>Endocrine disorders</b>			
<b>GOITRE</b>			
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	
<b>TOXIC NODULAR GOITRE</b>			
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	
<b>Infections and infestations</b>			
<b>ABDOMINAL ABSCESS</b>			
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	
<b>ABSCESS</b>			
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	
<b>APPENDICITIS</b>			
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
<b>CELLULITIS</b>		
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
<b>ERYSIPELAS</b>		
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
<b>GASTROENTERITIS</b>		
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
<b>HERPES ZOSTER</b>		
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
<b>OTITIS EXTERNA</b>		
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
<b>PELVIC ABSCESS</b>		
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

<b>PNEUMONIA</b>			
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	
<b>SKIN CANDIDA</b>			
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	
<b>STAPHYLOCOCCAL SEPSIS</b>			
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	
<b>UPPER RESPIRATORY TRACT INFECTION</b>			
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	
<b>Metabolism and nutrition disorders</b>			
<b>DIABETES MELLITUS</b>			
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	
<b>HYPERGLYCAEMIA</b>			
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	
<b>HYPOGLYCAEMIA</b>			
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	
<b>HYPOKALAEMIA</b>			
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	
<b>HYPONATRAEMIA</b>			
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	
<b>MALNUTRITION</b>			
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 %

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

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

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

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

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

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SALIVARY GLAND</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SINUS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SKIN</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SMALL BOWEL NOS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>STOMACH</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>SPLEEN</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SURGERY FOR METASTASIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>TEETH</b>		
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
<b>COLD</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	8 / 454 (1.76%)
occurrences (all)	0	10
<b>COMMON COLD</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)
occurrences (all)	0	4
<b>CONJONCTIVAL</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>CRAMPS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	3
<b>DULLED AFTER TAKING DRUG</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>DUMPING SYNDROM</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>DUMPING SYNDROME</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	6
<b>FACE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1

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

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

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

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

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

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

subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)
occurrences (all)	2	1
<b>MENORRHAGIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>MENSES UNREGULARLY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PRIAPISM</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>TESTICLE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>UNREGULARLY MENSES</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>URETHRA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	2	0
<b>VAGINA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>VAGINAL MUCOSITIS</b>		
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 occurrences (all)	0 / 454 (0.00%) 0	2 / 454 (0.44%) 2	
Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY INSUFICIENCY alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
ASTHMA alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	1 / 454 (0.22%) 1	1 / 454 (0.22%) 2	
BILATERAL PULMONARY INFILTRATES alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
BRONCHITIS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	2 / 454 (0.44%) 2	
BRONCHUS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
CATARRH alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 2	
CHEST/THORAX NOS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	2 / 454 (0.44%) 2	2 / 454 (0.44%) 2	
COLD			

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

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

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PULMONARY EMPHYSEME</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PULMONITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>RESPIRATORY DISTRESS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SINUS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SORE THROAT</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>THORAX</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	3
<b>THROAT IRRITATION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>TONSILITIS</b>		
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 occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
TRACHEITIS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
URTI alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
VOICE CHANGES alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
VOICE CHANGES (HOARSENESS) alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
WHEEZING (EXPIRATORY WHEEZING) alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
Investigations WEIGHT LOSS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	7 / 454 (1.54%) 9	64 / 454 (14.10%) 153	
Cardiac disorders ATRIAL FLUTTER alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)  CARDIAC (GENERAL)	1 / 454 (0.22%) 1	0 / 454 (0.00%) 0	

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

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

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

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

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

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>MIGRAINES</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>MOOD ALTERATION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	4 / 454 (0.88%)
occurrences (all)	1	6
<b>MUSCLE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)
occurrences (all)	0	8
<b>MOOD ALTERATION-DEPRSSION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>NEUROPATHY CRAMP HANDS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>NEUROPATHY SENSORY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	5
<b>NECK</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	2	0
<b>NEUROPATHY- SENSORY (FORMICATION IN HANDS)</b>		
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
<b>PARASTHESIAS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PARESTHESIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>PARESTHESIAS ON HANDS AND FEET</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PARESTHESIE FOOT BILATERAL</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PERIPHERAL POLYNEURITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PINS+NEEDLE SENSATION DOWN LEG</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>POOR CIRCULATION FINGER TIPS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	3
<b>POLYNEUROPATHY</b>		
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
TRENION 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 occurrences (all)	1 / 454 (0.22%) 1	0 / 454 (0.00%) 0	
Blood and lymphatic system disorders			
ABDOMINAL alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 5	
ANEMIA alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	1 / 454 (0.22%) 1	6 / 454 (1.32%) 17	
ANKLE SLIGHTY SWOLLEN alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
BLOCKED RIGHT EAR alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
DIC alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	1 / 454 (0.22%) 1	0 / 454 (0.00%) 0	
EDEMA FINGERS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
EDEMA LEGS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
EDEMA VISCERA alternative dictionary used: CTCAE 3.0			

subjects affected / exposed	0 / 454 (0.00%)	7 / 454 (1.54%)
occurrences (all)	0	11
<b>EDEMA, HEAD&amp;NECK</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	4 / 454 (0.88%)	284 / 454 (62.56%)
occurrences (all)	8	1555
<b>EDEMA, LIMBS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	3 / 454 (0.66%)	127 / 454 (27.97%)
occurrences (all)	3	386
<b>EDEMA, TRUNK/GENITAL</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	6
<b>EOSINOPHILIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	3
<b>EXCESSIVE LACRIMATION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>EYE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	3
<b>HEMATOMA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	5 / 454 (1.10%)
occurrences (all)	2	7
<b>HEMOGLOBIN</b>		
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	
<b>SIDEROPENIC ANAEMIA</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
<b>SWOLLEN GLAND (SUBMANDIBULAR)</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>SWOLLEN GLANDS</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
<b>UNSPECIFIED OEDEMA</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
<b>WATER RETENTION</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>Ear and labyrinth disorders</b>			
<b>AUDITORY/EAR -&gt; BLOCKED EARS WITH MAX</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>DEAFNESS</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	2	
<b>EAR NOISES</b>			
alternative dictionary used: CTCAE 3.0			

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

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

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

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>LACRIMATION INCREASED</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>MACULAR DEGENERATION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)
occurrences (all)	1	1
<b>NYSTAGMUS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>OCULAR</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>OCULAR SURFACE DISEASE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	18 / 454 (3.96%)
occurrences (all)	0	33
<b>OPHTALMIC TROUBLE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PHOTOPHOBIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>TEARING</b>		
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 occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
VISION DISTURB alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
VISUAL DISTURBANCE alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
VISUAL TROUBLE alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
WATERY EYE alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	1 / 454 (0.22%) 1	26 / 454 (5.73%) 84	
Gastrointestinal disorders ABDO PART, BLOATING alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
ABDOMEN alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	20 / 454 (4.41%) 38	29 / 454 (6.39%) 48	
ABDOMEN NOS alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 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

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

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

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

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

<b>DYSPHAGIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	7 / 454 (1.54%)
occurrences (all)	1	11
<b>DYSPHAGY (ANASTOMOSE)</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>EARLU SATIETY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>EARLY SATIETY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	2 / 454 (0.44%)	3 / 454 (0.66%)
occurrences (all)	3	7
<b>ENTERITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)
occurrences (all)	1	1
<b>EPIDGASTRIC HEAVINESSES</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>EPIGASTRALGIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	10 / 454 (2.20%)
occurrences (all)	0	19
<b>EPIGASTRALGY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>EPIGASTRIC BLOATING</b>		
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
<b>GASTRALGIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	10
<b>GASTRIC ACIDITY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	4
<b>GASTRIC DISCOMFORT</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>GASTRIC DISCONFORT</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>GASTRIC REFLUX</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	4 / 454 (0.88%)
occurrences (all)	1	4
<b>GASTRIC TROUBLE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>GASTRITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	4 / 454 (0.88%)	10 / 454 (2.20%)
occurrences (all)	4	15
<b>GASTRO ENTERITIS</b>		
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

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

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

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

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

<b>HAIR LOSS/ALOPECIA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HAND +FOOT SYNDROME</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HAND REACTION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HAND-FOOT</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HANDS ECZEMA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HERPES SIMPLEX</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HYPERPIGMENTATION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)
occurrences (all)	0	6
<b>HYPOPIGMENTATION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)
occurrences (all)	0	15
<b>INFECTED INSECT BITE</b>		
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
<b>NAILS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>NOT SPECIFIED</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)
occurrences (all)	2	1
<b>OCULAR</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>ONYCHORRHEXIS (UNGUEAL TOXICITY)</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>OTH DERMATITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PAPILLOMATOUS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	3
<b>PERIORBITAL ERYTHEMA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PHOTOSENSITIVITY</b>		
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
<b>PSORIASIS-LIKE LESIONS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PURITIS MEDIAL LEFT CALF</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>RASH</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>RASH (AXILLARY)</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>RASH RIGHT LEG</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>RECURRENT LESIONS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>RIGORS/CHILLS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>RING WORM</b>		
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
<b>SWELLING&amp;THICKENING OF SUBCUT. TISSU</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>TELANGIECTASIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>TRUNK</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>ULCERATION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>ULCER-POSSIBLE SPIDER BITE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>UNGUEAL TOXICITY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>WATER BLISTER (LOWER LEFT LEG)</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>WOUND</b>		
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

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

alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	3
<b>ARTHRITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)
occurrences (all)	5	2
<b>ARTHROSES</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>ARTHROSIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	2 / 454 (0.44%)	0 / 454 (0.00%)
occurrences (all)	10	0
<b>BURSITIS SHOULDER</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>BUTTOCK</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>CALF CRAMPS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>CALFS CRAMPS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>CERVICAL CONTRACTURE</b>		
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
<b>MUSCLE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	54 / 454 (11.89%)
occurrences (all)	1	122
<b>MUSCULAR CRAMPS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	7
<b>MUSLE SPASMS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>NECK</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	2 / 454 (0.44%)	1 / 454 (0.22%)
occurrences (all)	2	1
<b>NIGHT CRAMPS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>NOCTURAL CRAMPS (FEET+CALVES)</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>NUMBNESS IN KNEE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>NUMBNESS IN L KNEE</b>		
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	
<b>TENDOPATHY THIGH NIGHT</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)	
occurrences (all)	1	0	
<b>THORAX</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>TRISMUS</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>TRUNK</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>Infections and infestations</b>			
<b>ABDOMEN NOS</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>ABSCESS</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)	
occurrences (all)	0	4	
<b>AIRWAY</b>			
alternative dictionary used: CTCAE 3.0			
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)	
occurrences (all)	0	1	
<b>ATHLETE'S FOOT</b>			
alternative dictionary used: CTCAE 3.0			

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

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

subjects affected / exposed	1 / 454 (0.22%)	2 / 454 (0.44%)
occurrences (all)	1	2
<b>CONJUNCTIVITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)
occurrences (all)	0	5
<b>CYSTITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>CYSTITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	4 / 454 (0.88%)
occurrences (all)	0	8
<b>DENTAL</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	3 / 454 (0.66%)
occurrences (all)	0	3
<b>DENTAL-TOOTH</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>DIVERTICULITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>EAR INFECTION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>ESOPHAGITIS</b>		
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
<b>GASTRIC ABCESS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>GENITAL CONDYLOMA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>GRIPPAL SYNDROM</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HAND</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>HEAD</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	4
<b>HELICOBACTER PYLORI</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>HELICOBECTER PYLORI</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>HEPATITIS B</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
INFECTIOUS ACNE OUTBREAK		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
INFECTIOUS IN ORL SPHERE		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
INFECTIOUS WITH UNKNOWN ANC		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1

<b>INFLUENZA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	5 / 454 (1.10%)
occurrences (all)	0	5
<b>INFLUENZAL</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>JOINT</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>KIDNEY</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>LARYNGITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	2	0
<b>LEFT EAR INFECTION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>LEFT SIDE NECROTISING OTITIS LEFT EXTERNA</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>LIP</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>LIVER</b>		
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
<b>MYCOSIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>NAILS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>NOSE</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>OTH ACUTE GASTROENTERITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>OTITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	2
<b>PARANASAL</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>PELVIC</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>PELVIS</b>		
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
<b>RESPIRATORY INFECTION WITHOUT NEUTROPENI</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>RHINITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>RHINO-PHARINGITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>RHINOPHARYNGITIS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>RIGHT FOOT</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SALIVARY GLAND</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SEASONAL INFECTION</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>SHINGLES</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1

<b>SINUS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>SKIN</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	2 / 454 (0.44%)
occurrences (all)	0	2
<b>SMALL BOWEL NOS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>SPLEEN</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>STITCH ABSCESS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>STOMACH</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>TOOTH ABCESS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
<b>TOOTH ABSCESS</b>		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
<b>TOOTH INFECTION</b>		
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
VIROLOGICAL 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 occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
Metabolism and nutrition disorders ALAT=40N, ASAT=20N ( HEPATO TOXICITY) alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
ALT alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
ALT, AST alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
ANOREXIA alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	16 / 454 (3.52%) 27	55 / 454 (12.11%) 121	
BILIRUBIN INCREASE alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 2	
BILIRUBIN-INCREASE alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 1	
CHOLESTEROL alternative dictionary used: CTCAE 3.0 subjects affected / exposed occurrences (all)	0 / 454 (0.00%) 0	1 / 454 (0.22%) 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:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported