



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:

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

Subject disposition

Recruitment

Recruitment details:

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

Pre-assignment

Screening details:

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

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Observation

Arm description:

Follow-up after surgery without further antitumoral therapy

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

Arm title	Imatinib mesylate
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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

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

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Observation

Arm description:

Follow-up after surgery without further antitumoral therapy

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

Arm title	Imatinib mesylate
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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

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Consent withdrawn by subject	-	22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

Baseline characteristics

Reporting groups

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

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

End points

End points reporting groups

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

Primary: imatinib monotherapy failure free survival (IFS)

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

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

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

Statistical analyses

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

Notes:

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

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

Secondary: Relapse free Survival

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

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

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

Statistical analysis title	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

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

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

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
End point description:	
Overall survival is measured from the date of randomization to the date of death, whatever the cause. Alive patients are censored at the date of last follow-up or at the date of clinical cut-off whichever occurs the first.	
End point type	Secondary
End point timeframe:	
The same than the one used for the primary endpoint	

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

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

Statistical analysis title	Overall survival (OS - Adjusted)
Statistical analysis description:	
Adjusted for stratification factors (Risk Category, Resection, Tumor Site)	
Comparison groups	Observation v Imatinib mesylate
Number of subjects included in analysis	908
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.429
Method	Regression, Cox
Parameter estimate	Hazard ratio (HR)
Point estimate	0.882

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

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

Adverse events

Adverse events information

Timeframe for reporting adverse events:

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

Adverse event reporting additional description:

CRF for AEs contains pre-specified items + additional boxes for all "other" AEs. (xx% AEs are reported as "other" and are not reported as not available from the list of SOC).

AEs are evaluated using CTC grading, SAEs using MedDra. Non-SAEs has not been collected specifically, all AEs will be reported in non-SAE section.

Assessment type	Systematic
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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

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

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

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

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

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

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

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

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

RESPIRATORY DISTRESS alternative dictionary used: MedDRA 19 subjects affected / exposed 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	
OESOPHAGOGASTRODUODENOSCOPY			

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

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

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

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

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

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

OESOPHAGITIS alternative dictionary used: MedDRA 19 subjects affected / exposed 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		
OESOPHAGEAL PERFORATION 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		
PANCREATITIS 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	2 / 454 (0.44%) 0 / 2 0 / 0		
PANCREATITIS ACUTE 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		
PANCREATITIS NECROTISING 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		
PANCREATITIS RELAPSING 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 / 2 0 / 0	0 / 454 (0.00%) 0 / 0 0 / 0		
RECTAL HAEMORRHAGE alternative dictionary used: MedDRA 19				

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	4
REFLUX (OCCASIONAL)		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
REFLUX		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	5 / 454 (1.10%)
occurrences (all)	4	9
REFLUX 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>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>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>2 / 454 (0.44%)</p> <p>5</p>	
Skin and subcutaneous tissue disorders			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

subjects affected / exposed	1 / 454 (0.22%)	0 / 454 (0.00%)
occurrences (all)	1	0
VIRAL ILLNESS		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	1
VIRAL INFECTION		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	1 / 454 (0.22%)	1 / 454 (0.22%)
occurrences (all)	1	1
VIRAL INFECTION (COMMON COLD VIRUS)		
alternative dictionary used: CTCAE 3.0		
subjects affected / exposed	0 / 454 (0.00%)	1 / 454 (0.22%)
occurrences (all)	0	3
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:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported