Clinical trial results:
Phase III, multicentre, open-label, prospective randomised trial comparing Imatinib alone at 400mg versus 800mg daily versus Imatinib 400mg daily plus PEG Interferon-alpha with newly diagnosed chronic myeloid leukaemia

Summary

EudraCT number	2004-001622-24
Trial protocol	IE
Global end of trial date	15 January 2014

Results information

Result version number	v1 (current)
This version publication date	08 September 2016
First version publication date	08 September 2016

Trial information

Trial identification

Sponsor protocol code	Spirit Version 16

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Newcastle upon Tyne Hospitals NHS Trust
Sponsor organisation address	Freeman Hospital, Freeman Road, Newcastle upon Tyne, United Kingdom, NE7 7DN
Public contact	Spirit Trials Secretary, Spirit Trials Office, 0044 0191 282 0904, enu-tr.spirittrials@nhs.net
Scientific contact	Stephen O'Brien, Newcastle Clinical Trials Unit, 0044 0191 282 0904, stephen.o'brien@ncl.ac.uk

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	10 February 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 January 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine overall survival at 5 years

Protection of trial subjects:

No specific protection in addition to standard care offered to chronic myeloid leukaemia patients

Background therapy: -

Evidence for comparator:

The rationale for combining imatinib with interferon alpha is based on pre-clinical data that demonstrates additive to synergistic anti-proliferative activity of these agents against leukaemic cells in vitro. Clinical studies have shown that the agents, when given in combination, produce higher rates of cytogenetic responses despite using low doses of imatinib.
The rationale for using a higher dose of imatinib comes from early studies in newly diagnosed CML patients in chronic phase where a higher cytogenetic response was seen in the higher dose (800mg/day) group than the standard dose (400mg/day) group, 74% versus 59% respectively.

Actual start date of recruitment	03 June 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	United Kingdom: 259
Worldwide total number of subjects	259
EEA total number of subjects	259

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)	208
From 65 to 84 years	51

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment opened in June 2005 and closed on 1st February 2009. During that period 259 patients were recruited at 66 sites in the UK.

Pre-assignment

Screening details:

Patients only entered screening if they had newly diagnosed chronic myeloid leukaemia in chronic phase. Patients could not be taking any drug therapy for their leukaemia other than hydroxycarbamide on analgrelide and have not undergone bone marrow transplantation. All screening assessments had to be carried out within 14 days of randomisation.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Imatinib 400mg

Arm description:

Imatinib 400mg daily

Arm type	Active comparator
Investigational medicinal product name	Imatinib
Investigational medicinal product code	
Other name	Glivec
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Take one 400mg tablet once daily

Arm title	Imatinib 800mg

Arm description:

Imatinib 800mg daily

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

Dosage and administration details:

Take one 400mg tablet twice daily

Arm title	Imatinib 400mg + INF

Arm description:

Pegylated interferon-alpha and imatinib

Arm type	Experimental

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

Dosage and administration details:

Take one 400mg tablet once daily

Investigational medicinal product name	pegylated interferon-alpha
Investigational medicinal product code	
Other name	Pegasys
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Starting with dose of 90 micrograms of Pegasys to be given once a week every 4 weeks for 3 weeks, followed by once a week every 2 weeks for a further 4 weeks then once a week every week for 6 weeks then dose increased to 180 micrograms once every week for rest of study period.

Number of subjects in period 1	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF
Started	99	96	64
Start Of Treatment	98	96	64
Treatment Discontinuation	98	96	64
Completed	52	39	12
Not completed	47	57	52
Adverse event, serious fatal	4	1	2
Consent withdrawn by subject	1	4	3
Adverse event, non-fatal	7	26	26
Other Reasons	4	10	4
Lost to follow-up	1	-	-
Lack of efficacy	28	16	14
Protocol deviation	2	-	3

Period 2

Period 2 title	Off Treatment Period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Imatinib 400mg
Arm description: Imatinib 400mg daily	
Arm type	Active comparator
Investigational medicinal product name	Imatinib
Investigational medicinal product code	
Other name	Glivec
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Take one 400mg tablet once daily	
Arm title	Imatinib 800mg
Arm description: Imatinib 800mg daily	
Arm type	Experimental
Investigational medicinal product name	Imatinib
Investigational medicinal product code	
Other name	Glivec
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Take one 400mg tablet twice daily	
Arm title	Imatinib 400mg + INF
Arm description: Pegylated interferon-alpha and imatinib	
Arm type	Experimental
Investigational medicinal product name	Imatinib
Investigational medicinal product code	
Other name	Glivec
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Take one 400mg tablet once daily	
Investigational medicinal product name	pegylated interferon-alpha
Investigational medicinal product code	
Other name	Pegasys
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Starting with dose of 90 micrograms of Pegasys to be given once a week every 4 weeks for 3 weeks, followed by once a week every 2 weeks for a further 4 weeks then once a week every week for 6 weeks then dose increased to 180 micrograms once every week for rest of study period.

Number of subjects in period 2	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF
Started	52	39	12
Completed	52	39	12

Baseline characteristics

Reporting groups	
Reporting group title	Imatinib 400mg
Reporting group description: Imatinib 400mg daily	
Reporting group title	Imatinib 800mg
Reporting group description: Imatinib 800mg daily	
Reporting group title	Imatinib 400mg + INF
Reporting group description: Pegylated interferon-alpha and imatinib	

Reporting group values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF
Number of subjects	99	96	64
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	78	80	50
From 65-84 years	21	16	14
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	52.414	52.073	53.75
standard deviation	± 13.771	± 13.406	± 13.406
Gender categorical Units: Subjects			
Female	39	36	22
Male	60	60	42
Weight Units: kg			
arithmetic mean	77.426	81.867	77.389
standard deviation	± 16.686	± 19.63	± 15.698
Height Units: meters			
arithmetic mean	1.699	1.713	1.707
standard deviation	± 0.089	± 0.094	± 0.109
BMI			
Body Mass Index			
Units: Kg/(m^2)			
arithmetic mean	26.639	27.739	26.3
standard deviation	± 4.987	± 6.708	± 4.003

Reporting group values	Total		
Number of subjects	259		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	208		
From 65-84 years	51		
85 years and over	0		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	97		
Male	162		
Weight Units: kg			
arithmetic mean			
standard deviation	-		
Height Units: meters			
arithmetic mean			
standard deviation	-		
BMI			
Body Mass Index			
Units: Kg/(m^2)			
arithmetic mean			
standard deviation	-		

Subject analysis sets

Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

The FAS is defined as all randomised patients who received study medication at least once. Patients will be analysed according to the treatment group to which they were randomised, rather than by the actual treatment they were administered. The FAS is the primary population of interest for all efficacy analyses.

Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who are randomised into the study and who received study medication at least once will be considered evaluable for the Safety Set. This is the same definition as the FAS. However, in the event that a patient receives study medication other than that to which they have been randomised, analyses based on the Safety Set will be performed using the actual treatment group that was administered and

so will be different to the FAS. All safety tables will be based on the Safety Set.

Reporting group values	Full Analysis Set	Safety Set	
Number of subjects	258	258	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	207	207	
From 65-84 years	51	51	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	52.659	52.659	
standard deviation	± 13.155	± 13.155	
Gender categorical Units: Subjects			
Female	96	96	
Male	162	162	
Weight Units: kg			
arithmetic mean	78.579	78.579	
standard deviation	± 18.996	± 18.996	
Height Units: meters			
arithmetic mean	1.706	1.706	
standard deviation	± 0.096	± 0.096	
BMI			
Body Mass Index			
Units: Kg/(m^2)			
arithmetic mean	26.994	26.994	
standard deviation	± 5.558	± 5.558	

End points

End points reporting groups

Reporting group title	Imatinib 400mg
Reporting group description: Imatinib 400mg daily	
Reporting group title	Imatinib 800mg
Reporting group description: Imatinib 800mg daily	
Reporting group title	Imatinib 400mg + INF
Reporting group description: Pegylated interferon-alpha and imatinib	
Reporting group title	Imatinib 400mg
Reporting group description: Imatinib 400mg daily	
Reporting group title	Imatinib 800mg
Reporting group description: Imatinib 800mg daily	
Reporting group title	Imatinib 400mg + INF
Reporting group description: Pegylated interferon-alpha and imatinib	
Subject analysis set title	Full Analysis Set
Subject analysis set type	Full analysis

Subject analysis set description:

The FAS is defined as all randomised patients who received study medication at least once. Patients will be analysed according to the treatment group to which they were randomised, rather than by the actual treatment they were administered. The FAS is the primary population of interest for all efficacy analyses.

Subject analysis set title	Safety Set
Subject analysis set type	Safety analysis

Subject analysis set description:

All patients who are randomised into the study and who received study medication at least once will be considered evaluable for the Safety Set. This is the same definition as the FAS. However, in the event that a patient receives study medication other than that to which they have been randomised, analyses based on the Safety Set will be performed using the actual treatment group that was administered and so will be different to the FAS. All safety tables will be based on the Safety Set.

Primary: Overall Survival at 5 Years

End point title	Overall Survival at 5 Years
End point description: To compare overall survival in the three arms at 5 years	
End point type	Primary
End point timeframe: 5 years	

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98[1]	96[2]	64[3]	
Units: Patients Alive at 5 Years				
Patients Alive	27	19	8	
Patients Died	71	77	56	

Notes:

[1] - Full Analysis Set

[2] - Full Analysis Set

[3] - Full Analysis Set

Attachments (see zip file)	Kaplan-Meier plot/NCUSPIRITKM.png

Statistical analyses

Statistical analysis title	Kaplan-Meier

Statistical analysis description:

The proportion of patients surviving to 5 years will be summarised by treatment group for the FAS.
A Kaplan-Meier Plot will be produced using the following method of censoring:
Patients discontinuing study medication for any reason other than death will be censored at the time of discontinuation from study drug. For Overall Survival, irrespective of any further follow-up/last contact information.

Comparison groups	Imatinib 800mg v Imatinib 400mg v Imatinib 400mg + INF
Number of subjects included in analysis	258
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0246 [4]
Method	Logrank

Notes:

[4] - The Log-Rank test was planned in the protocol, however due to the lack of sample size, the study is underpowered, and therefore this hypotesis test will not be performed.

Secondary: Molecular Response

End point title	Molecular Response

End point description:

To compare the level of molecular response (BCR-ABL/ABL ratio by real time PCR after one year of study therapy in each of the treatment arms.

End point type	Secondary

End point timeframe:

After 1 year of therapy (Visit 7).

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98[5]	96[6]	64[7]	
Units: Patients with Molecular Response				
Molecular Response 3 (MR3) - PCR <0.1%	23	33	18	
Molecular Response 4 (MR4) - PCR <0.01%	7	9	10	

Molecular Response 4.5 (MR4.5) - PCR <0.0032%	3	3	5	
No Molecular Response	65	51	31	

Notes:

[5] - Full Analysis Set

[6] - Full Analysis Set

[7] - Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Progression

End point title	Time to Progression

End point description:

To compare time to progression in the three arms of the study according to progression definitions in protocol.

End point type	Secondary

End point timeframe:

From start of therapy to protocol definition of progression.

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	96[8]	93[9]	64[10]	
Units: Months				
arithmetic mean (standard deviation)	40.4 (± 23.94)	34.38 (± 23.69)	22.22 (± 21.77)	

Notes:

[8] - Selection of Patients with Available data for the Endpoint from Full Analysis Set

[9] - Selection of Patients with Available data for the Endpoint from Full Analysis Set

[10] - Selection of Patients with Available data for the Endpoint from Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Treatment Failure

End point title	Time to Treatment Failure

End point description:

To compare time to treatment failure in the three arms of the study.

End point type	Secondary

End point timeframe:

From start of treatment to documented protocol defined treatment failure.

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98[11]	96[12]	64[13]	
Units: Months				
arithmetic mean (standard deviation)	44.57 (± 27.37)	50.98 (± 24.41)	47.36 (± 25.58)	

Notes:

[11] - Full Analysis Set

[12] - Full Analysis Set

[13] - Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Secondary: Rate of Cytogenetic Response

End point title	Rate of Cytogenetic Response

End point description:

To compare rate of cytogenetic responses (major and complete) at one year and the cumulative incidence of such responses with each of the regimens.

End point type	Secondary

End point timeframe:

At 1 year after study treatment started (Visit 7).

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98[14]	96[15]	64[16]	
Units: Patients				
No cytogenetic response	35	22	17	
Major cytogenetic response	36	40	26	
Complete cytogenetic response	27	34	21	

Notes:

[14] - Full Analysis Set

[15] - Full Analysis Set

[16] - Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Haematological Response Rate

End point title	Complete Haematological Response Rate

End point description:

To compare the rates of complete haematological response in patients treated with all regimens.

End point type	Secondary

End point timeframe:

Whole 5 year study period

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98[17]	96[18]	64[19]	
Units: Patients				
Hematological Responders	93	88	61	
Hematological Non-Responders	5	8	3	

Notes:

[17] - Full Analysis Set Patients

[18] - Full Analysis Set Patients

[19] - Full Analysis Set Patients

Statistical analyses

No statistical analyses for this end point

Secondary: Tolerability

End point title	Tolerability

End point description:

To compare tolerability of these regimens.

End point type	Secondary

End point timeframe:

Whole 5 year study period.

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98[20]	96[21]	64[22]	
Units: Patients with AE Related to Study Drug				
Patients who experienced AEs Related to Study Drug	76	89	55	
Patient without AEs Related to Study Drug	22	7	9	

Notes:

[20] - Full Analysis Set

[21] - Full Analysis Set

[22] - Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Secondary: Quality of Life

End point title	Quality of Life

End point description:

To assess quality of life on each of the 3 arms.

End point type	Secondary

End point timeframe:

At 1 year from the baseline visit (visit 7).

End point values	Imatinib 400mg	Imatinib 800mg	Imatinib 400mg + INF	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98[23]	96[24]	64[25]	
Units: Quality of life Scores				
arithmetic mean (standard deviation)				
FACT-G / Total Score / Baseline	83.96 (± 15.57)	82.13 (± 16.99)	84.13 (± 15.03)	
EQ-5D / VAS Score / Baseline	58 (± 35.58)	54.82 (± 32.94)	69.71 (± 30.69)	
FACT-BRM / Total Outcome Index / Baseline	82.21 (± 18.07)	78.39 (± 19.83)	85.12 (± 18.7)	
FACT-G / Total Score / 12 Months	87.66 (± 16.57)	82.21 (± 19.1)	88.26 (± 11.87)	
EQ-5D / VAS Score / 12 Months	71.34 (± 32.03)	70.5 (± 27.88)	71.25 (± 33.33)	
FACT-BRM / Total Outcome Index / 12 Months	84.92 (± 17.7)	77.91 (± 24.03)	83.31 (± 14.81)	

Notes:

[23] - Full Analysis Set

[24] - Full Analysis Set

[25] - Full Analysis Set

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From date of signed informed consent to 4 weeks post last dose of study drug taken for each subject	
Adverse event reporting additional description:	
Adverse events collected by physician, reported by patient or from laboratory tests	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	Reported Term
Dictionary version	0

Reporting groups	
Reporting group title	Imatinib 400mg
Reporting group description:	
Imatinib 400mg daily	
Reporting group title	Imatinib 400mg + INF
Reporting group description:	
Pegylated interferon-alpha and imatinib	
Reporting group title	Imatinib 800mg
Reporting group description:	
Imatinib 800mg daily	

Serious adverse events	Imatinib 400mg	Imatinib 400mg + INF	Imatinib 800mg
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 89 (21.35%)	10 / 62 (16.13%)	24 / 107 (22.43%)
number of deaths (all causes)	11	9	6
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE CORONARY SYNDROME			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ACUTE RENAL FALIURE			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA (GI)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADENOCARCINOMA OF GI ORIGIN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ADMITTED TO HOSPITAL WITH SEVERE BONE PAIN ? DUE TO LOW WCC			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
AGITATION DUE TO INFECTED RIGHT TOTAL KNEE REPLACEMENT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ALT RESULT 174-TRIAL DRUGS TEMPORARY STOPPED AWAITING HEPATOLOGY OPINION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAEMIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANGIOEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

BLADDER CANCER			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLAST CRISIS OF CML			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
BLURRED VISION (PERSISTANT MIGRAINE AURA)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BONE PAIN IN PELVIS AND THIGHS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CALF HAEMATOMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CAMPYLOBACTER GASTROENTERITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARCINOMA OF PROSTATE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARDIAC ISCHEMIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CEREBRAL INFARCTION			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHEST INFECTION			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHRONIC RENAL FAILURE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CML TRANSFORMED TO AML			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
CONFUSION DUE TO INFECTED RIGHT TOTAL KNEE REPLACEMENT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COUGH AND MILD FEVER			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CVA/ VENOUS SINUS THROMBOSIS WITH SECONDARY HAEMORRHAGE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DEHYDRATION			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DERANGED LFTS (BORDERLINE GRADE 3 TOXICITY) - ZONE 3			

HEPATIC NECROSIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA AND VOMITING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIFFUSE LARGE B-CELL LYMPHOMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EPIGASTRIC PAIN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EXACERBATION OF COPD			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FAST ATRIAL FIBRILATION AND GRADE 3 PLATELET TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FATIGUE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEVER (WITH NORMAL NEUTROPHILS)			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GLOSSAL SWELLING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GRADUAL DECREASE IN FULL BLOOD COUNT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEADACHES VOMITING, LOOSE BOWELS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATO-TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INFECTIVE EXACERBATION OF FIBROSING ALVEOLITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INSOMNIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTENTIONAL OVERDOSE OF			

ZOPICLONE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT PNEUMOTHORAX			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
LEFT SIDED STROKE (CVA)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEFT SUBCONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LICHEN PLANUS ON TONGUE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOSS OF CONCIOUSNESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOW PHOSPHATES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER LEFT ABDOMINAL PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENINGOCOCCAL SEPSIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MENORRAGHIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA/SICKNESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEUTROPENIA			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PAIN IN RIGHT LEG FOLLOWING BONE MARROW PROCEDURE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PELVIC AND THIGH BONE PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROBABLE ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PROSTATE CANCER			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PT PARTNER MISCARRIED			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYREXIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RAISED CREATININE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RENAL FAILURE			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RESTRICTIVE CARDIOMYOPATHY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RIGORS / CHILLS - FLUE LIKE SYMPTOMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEPTIC EVENT POST TOTAL KNEE REPLACEMENT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEVERE LOW PRESSUREHEADACHE AS A RESULT OF A CSF LEAK.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEVERE MUSCULOSKELETAL PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SEVERE THROAT INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHINGLES			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SHORTNESS OF BREATH (PULMONARY OEDEMA&PNEUMONIA)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SWOLLEN UPPER LIP			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TOOK AN OVERDOSE OF IMATINIB			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSFORMATION TO PRE B- CELL ALL.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VERY LOW MOOD			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITTING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WORSENING OF CHRONIC FIBROSING ALVEOLITIS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Imatinib 400mg	Imatinib 400mg + INF	Imatinib 800mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	88 / 89 (98.88%)	61 / 62 (98.39%)	91 / 107 (85.05%)
General disorders and administration site conditions			
"FRAGILE SKIN"			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
1 WEEK OF FLU LIKE SYMPTOMS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
2 DAYS OF FLU LIKE SYMPTOMS AFTER PEG-INTERFON			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ACUTE VERTIGO, LOUD NOISE, NUMBNESS OF FACE. ATYPICAL MENIERE'S DISEASE.			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
? INFECTED RIGHT KNEE JOINT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
? PITYRIASIS LICHENOIDES CHRONICA ON LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ABDOMENAL PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ABDOMINAL BLOATING			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ABDOMINAL CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	2 / 107 (1.87%)
occurrences (all)	0	1	2
ABDOMINAL DISCOMFORT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL OEDEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN			
subjects affected / exposed	1 / 89 (1.12%)	3 / 62 (4.84%)	5 / 107 (4.67%)
occurrences (all)	1	3	5
ABDOMINAL PAIN AND OCCASIONAL CRAMPS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ABDOMINAL PAIN, INCREASED BURPING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ABNORMAL LFT'S			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ABSOULTE NEUTROPHIL COUNT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ACHES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ACHES AND PAINS IN BOTH THIGHS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ACHES AND PAINS IN JOINTS			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ACHES AND PAINS IN LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ACHES IN BODY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	4
ACHES IN HIPS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ACHES IN LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
ACHING BONES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ACHING JOINTS			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
ACHING JOINTS AND FLU SYMPTOMS RELATED TO FLU JAB			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ACHING LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
ACHING LEGS, SHOULDERS AND CALVES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ACHING MUSCLES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
ACHING THIGH BONES			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ACHING THIGHS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ACHING THIGHS AND GROIN AREAS BILATERALLY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ACID REFLUX			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
ACOUSTIC NUEROMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
AGGITATION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
AGITATION/ ANXIETY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ALLERGIC REACTION (SWOLLEN TONGUE AND NECK)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ALLERGIC REACTION -SWOLLEN TONGUE DURING A MEAL. CAUSE UNKNOWN OF WHICH FOOD ITEM			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ALLERGIC REACTION ? CAUSE AFFECTS TONGUE SWOLLEN AND FLUID COLLECTS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ALLERGIC REACTION AT SITE OF PNEUMOVAX INJECTION (ARM)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0

ALLERGIC REACTION TO LISINOPRIL			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ALTERED BOWEL FUNCTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ALTERED SENSE OF TASTE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ALTERED TASTE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ALTERNATING CONSTIPATION AND DIARRHOEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ALTERNATING DIARRHOEA AND CONSTIPATION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ALTHRALGIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
AMENORRHOEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ANAEMIA			
subjects affected / exposed	7 / 89 (7.87%)	5 / 62 (8.06%)	5 / 107 (4.67%)
occurrences (all)	8	11	6
ANAEMIA HB 10.9G/DL			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ANAL FISSURE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
ANEMIA			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
ANGINA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ANKEL OEDEMA, PUFFY EYES AND FEW CHEST SOUNDS AT RIGHT BASE.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ANKLE ODEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ANKLE OEDEMA			
subjects affected / exposed	1 / 89 (1.12%)	4 / 62 (6.45%)	3 / 107 (2.80%)
occurrences (all)	1	5	3
ANOREXIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	5 / 107 (4.67%)
occurrences (all)	0	0	5
ANXIETY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ANXIOUS/PALPITATIONS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
APHTHOUS ULCERS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ARTHRALGIA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	3 / 107 (2.80%)
occurrences (all)	0	2	3
ARTHRALGIA (R LEG)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ARTHRALGIA + MYALGIA			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ARTHRALGIA ONLY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ARTHRALGIA/MYALGIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ARTHROSCOPY LEFT KNEE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ASTENIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ATTACK OF GOUT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BACK ACHE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
BACK AND HIP PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BACK PAIN			
subjects affected / exposed	2 / 89 (2.25%)	2 / 62 (3.23%)	5 / 107 (4.67%)
occurrences (all)	2	2	5
BACK PAIN, RSIDED LOWER RIBS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BACKACHE AND NECK PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BI-LATERAL SUBMANDIBULAR			

LYMPHADENOPATHY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BILATERAL ANKLE OEDEMA IN BOTH LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BILATERAL ANKLE RASH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
BILATERAL LOIN PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BILATERAL OEDEMA IN BOTH LEGS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
BILIARY REFLUX			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BLACKOUTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLEED INTO RIGHT EYE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BLEEDING AROUND EYES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
BLEEDING FROM BOWELS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLEEDING GIMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BLEEDING LEFT EYE			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BLISTERING RASH ON LEGS WHICH BECAME INFECTED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLOOD BLISTER IN MOUTH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLOOD BLISTER ON RIGHT WRIST			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLOOD BLISTERS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLOOD BLISTERS AROUND WRISTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLOOD SHOT EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLOODSHOT LEFT EYE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLOTCHY SKIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLUE TINGE TO TOES AND COLD FEET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BLURRED VISION			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	2	1	1
BLURRED VISION - BILATERAL			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BLURRED VISION LEFT EYE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
BLURRED VISION.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BONE AND JOINT PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BONE PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	7 / 107 (6.54%)
occurrences (all)	1	0	7
BONE PAIN, - BACK, LEGS AND RIBS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BONEY ACHES AND PAIN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
BONEY PROMINENCE RIGHT ELBOW - NEW			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BOWEL FREQUENCY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BREAST INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BREATHLESSNESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	2	0	2
BRONCHITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1

BRUISED AROUND INJECTION SITE FROM INSULIN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
BRUISED LEGS (VERY LARGE BRUISES)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BRUISING			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	2	0	1
BRUISING OF BALL OF R FOOT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BRUISING OVER RIBS ON RIGHT SIDE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BRUSING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
BURNING HEAD AND RED FACE LASTING 4-5HRS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BURNT RIGHT HAND			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
BURSITIS IN RIGHT FOOT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
BUZZING IN EARS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CALF CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
CARDIAC OTHER - MILD DIZZINESS THOUGHT TO BE MILD			

HYPOTENSION ALTHOUGH BP NOT MEASURED AT CLINIC			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CATARACT REPAIR LEFT EYE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CATTERACT RIGHT EYE FOLLOWING LASER SURGERY FOR RETINA DETACHMENT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CELLULITIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CENTRAL CHEST PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CENTRAL CHEST PAIN RADIATING TO MID BACK			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CHEST HEAVYNESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CHEST INFECTION			
subjects affected / exposed	10 / 89 (11.24%)	1 / 62 (1.61%)	6 / 107 (5.61%)
occurrences (all)	20	1	6
CHEST INFECTION NOS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CHEST INFECTION-DETAILS NOT KNOWN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CHEST PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
CHEST PAIN WITH COLD			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CHEST PAINS AT NIGHT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CHESTY COUGH FROM POST NASAL DRIP			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
CHICKEN POX			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CHILLS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CHRAMP			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CHRONIC OBSTRUCTIVE AIRWAYS DISEASE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CIRCUMORBITAL OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
COGNATIVE IMPAIRMENT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
COLD			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
COLD - RUNNY NOSE AND SORE THROAT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
COLD AND FLU SYMPTOMS			

subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
COLD AND FLU SYMPTOMS RELATED TO INTERFERON INJECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
COLD AND UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
COLD FINGERS AND TOES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
COLD INTOLERANCE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
COLD SORE			
subjects affected / exposed	1 / 89 (1.12%)	2 / 62 (3.23%)	1 / 107 (0.93%)
occurrences (all)	1	2	1
COLD SORE ON LOWER LIP			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
COLD SORE UPPER LIP			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
COLD SORES TO NOSE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
COLD SWEATS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
COLD SYMPTOMS			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	0 / 107 (0.00%)
occurrences (all)	0	3	0
COLD VIRUS WITH SINUS DISCHARGE			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
COMMON COLD VIRUS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
COMPLAINS OF A REDUCED APPETITE SINCE COMMENCING GLIVEC			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CONJUCTIVITIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CONJUNCTIVAL INFECTION (RIGHT EYE)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CONJUNCTIVITIS			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	2 / 107 (1.87%)
occurrences (all)	0	2	2
CONSTIPATION			
subjects affected / exposed	2 / 89 (2.25%)	1 / 62 (1.61%)	5 / 107 (4.67%)
occurrences (all)	2	1	5
CONTINUAL UPSET STOMACH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CORYZAL SYMPTOMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
COUGH			
subjects affected / exposed	4 / 89 (4.49%)	3 / 62 (4.84%)	2 / 107 (1.87%)
occurrences (all)	4	3	2
COUGH AND SORE THROAT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
COUGH AT NIGHT			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
COUGH WITH SPUTUM			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
COUGH/VIRAL INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
COVERED IN RASH:HOT AND RED ALL OVER			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
CRAMP			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMP IN HANDS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
CRAMPS			
subjects affected / exposed	1 / 89 (1.12%)	4 / 62 (6.45%)	5 / 107 (4.67%)
occurrences (all)	1	4	5
CRAMPS HANDS AND LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS IN BOTH HANDS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CRAMPS IN BOTH LOWER LEG AREAS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS IN CALVES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CRAMPS IN FEET			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS IN FINGERS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CRAMPS IN LEG AND ABDOMEN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS IN LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS INTERMITTENTLY IN FINGERS AND FEET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS ON CHEST WALL			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
CRAMPS TO KNEE AT NIGHT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS, NOT SPECIFIED WHERE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CRAMPS-NOT SPECIFIED			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
CRAMPY ABDOMINAL PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CRAMPY PAIN IN LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
CROHN'S DISEASE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0

CROHNS FLARE UP			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CUT OVER LEFT EYE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
CYST ON HEAD			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CYTOPENIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CYTOPENIA LOW BLOOD COUNT PLATELETS 65 HAEMAGLOBIN 7.0			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
CYTOPENIC			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
DAY/NIGHT SWEATS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DECREASE IN APPETITE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DECREASED APPETITE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DECREASED NEUTROPHILS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DECREASED PLATELETS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DECRESING NEUTROPHIL COUNT SINCE RECOMMENCING INTERFERON			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DEEP VEIN THROMBOSIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DEGENERATIVE CHANGES TO LEFT KNEE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DENTAL ABCESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DENTAL ABCESS LEFT SIDE OF FACE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DEPRESSED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DEPRESSION			
subjects affected / exposed	3 / 89 (3.37%)	6 / 62 (9.68%)	5 / 107 (4.67%)
occurrences (all)	3	6	5
DERANGED LIVER FUNCTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DERANGED LIVER FUNCTION TESTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DERMATOLOGY/SKIN OTHER: SKIN IRRITATION BUT NO RASH OR FLAKINESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIABETES TYPE II			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DIAHORREA			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
DIARRHEA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIARRHEOA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
DIARRHOEA			
subjects affected / exposed	20 / 89 (22.47%)	12 / 62 (19.35%)	29 / 107 (27.10%)
occurrences (all)	25	18	49
DIARRHOEA & VOMITING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIARRHOEA & VOMITING.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIARRHOEA - INTERMITTENT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIARRHOEA AND VOMITING BUG			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIARRHOEA EPISODES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIARRHOEA X2 EPISODES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DIARRHOEA, NAUSEA AND DIZZINESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIARRHOEA/NAUSEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0

DIARROHEA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DIFFUSE RASH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DISCHARGE FROM EARS AND PUFFY EYES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DISCOLORATION OF TEETH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIVERTICULITIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	3
DIVERTICULITIS (PREVIOUSLY REPORTED)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIZZINESS			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	2	0	3
DIZZINESS/ SPINNING HEAD			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DIZZY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DIZZYNESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DROP IN COUNTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DRY AND ITCHY EYES			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DRY COUGH			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
DRY EYELIDS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DRY EYES			
subjects affected / exposed	3 / 89 (3.37%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	3	0	0
DRY LIPS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DRY MOUTH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DRY MOUTH AND DRY ITCHY SKIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
DRY PENIS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DRY SKIN			
subjects affected / exposed	3 / 89 (3.37%)	0 / 62 (0.00%)	4 / 107 (3.74%)
occurrences (all)	3	0	4
DRY SKIN TO RIGHT AND LEFT SIDES OF FACE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DRY THROAT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
DRYNESS OF SCALP			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0

DULL ACHE IN THIGH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DYSPEPSIA			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	5 / 107 (4.67%)
occurrences (all)	0	2	5
DYSPHAGIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
DYSPNEA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
DYSPNOEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	1	0	2
EAR ACHE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
EAR INFECTION			
subjects affected / exposed	3 / 89 (3.37%)	4 / 62 (6.45%)	1 / 107 (0.93%)
occurrences (all)	3	4	1
ECZEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ECZEMA ON FOREHEAD			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
ECZEMA RIGHT AXILLA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ECZEMA TO CALF			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ECZEMATOUS RASH TO LEGS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0

ECZEMATOUS TYPE LESIONS ON BOTH PALMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ELEVATED ALT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ELEVATED AST			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	3
ELEVATED BILIRUBIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ELEVATED GAMMA GT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ELEVATED GGT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ELEVATED LIVER FUNCTION TESTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
EPIGASTRIC DISCOMFORT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
EPIGASTRIC PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
EPIGASTRIC TENDERNESS			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	0 / 107 (0.00%)
occurrences (all)	0	2	0
EPISODE OF PASSING BLACK STOOLS FOR 4 DAYS (NOT SPECIFIED)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
EPISODES OF CRAMP			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
EPISODES OF CRAMP TO TOES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
EPISODIC EXPLSIVE DIARRHOEA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
EPISTAXIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ERECTILE DYSFUNCTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ERYTHEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ERYTHEMA INJECTION SITE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ERYTHEMA PEGASYS INJECTION SITE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ERYTHEMATOUS CONFLUENT MACULAR RASH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
EXACERBATION OF DIVERTICULITIS - ABDOMINAL PAIN AND DIARRHOEA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
EXAMINATION IN PAIN BUT SEEMS VERY OUT OF PROPORTION TO LIKELY SPLENOMEGALY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
EXCESSIVE PERSPIRATION			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
EXCESSIVELY TIRED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
EXTREMITY LIMB PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
EYE INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
EYE-WATERING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
EYES BLOOD SHOT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FACE PAIN - AROUND JAW AREA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FACIAL ODEMA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	2
FACIAL OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FACIAL OEDEMA (PERI-ORBITAL)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FACIAL PUFFINESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FACIAL RASH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FACIAL SWELLING			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	2 / 107 (1.87%)
occurrences (all)	0	1	3
FACIAL SWELLING AROUND THE EYES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FACIAL SWELLING IN MORNING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FAINTED			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FALL			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
FALL FROM STAIRS (DISLOCATED RIGHT ELBOW, BROKE 1 RIB)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FATIGUE			
subjects affected / exposed	13 / 89 (14.61%)	18 / 62 (29.03%)	24 / 107 (22.43%)
occurrences (all)	23	24	32
FATIGUE -POST PEGASYS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FATIGUE/MUSCLE WEAKNESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FATIGUR			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FATIQUE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FEELING 'COLD'			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FEELING BIT SICKLY AND VOMITED X1			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FEELING COLD			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FEELING HOT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FEELING LETHARGIC			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FEELING MORE MOODY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FEELING MORE TIRED			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FEELING TIRED & UNWELL			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FEELS TIRED & TENDS TO FALL ASLEEP EASILY, NOT GOT THE SAME ENERGY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FEET OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FEINT WITH FALL,SORE RIGHT SHOULDER.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FELT FAINT			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FELT SICK (SOMETIMES VOMIT)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FEVER			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	0 / 107 (0.00%)
occurrences (all)	0	2	0
FIBROMYALGIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FINGER INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FINGER SWELLING			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FLASHING HEADACHES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FLATULANCE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FLORID ITCHING ERYTHEMATOUS SKIN : TRUNK BACK ARMS AND LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FLORID TOTAL BODY RASH, NON ITCHY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FLU			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FLU LIKE SYMPTOMS			

subjects affected / exposed	1 / 89 (1.12%)	5 / 62 (8.06%)	0 / 107 (0.00%)
occurrences (all)	1	5	0
FLU LIKE SYMPTOMS FOLLOWING FIRST PEG INTERFERON INJECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FLU- LIKE SYMPTOMS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FLU-LIKE ILLNESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FLU-LIKE SYNDROME			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FLUID RETENTION			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	3 / 107 (2.80%)
occurrences (all)	2	1	6
FLUID RETENTION AND WEIGHT GAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FLUID RETENTION TO EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FOLLICULAR RASH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FOLLICULITIS FOREHEAD			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FOLLICULITIS RIGHT ARMPIT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FRACTURED LEFT FIFTH METATARSAL			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FRACTURED LEFT RADIUS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FRACTURED STERUM			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
FRACTURED TIP OF RIGHT LATERAL MALLEOLUS.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FRESH BLEEDING WHEN OPENING BOWELS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FULLNESS RIGHT BREAST			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
FUNGAL RASH IN PERIANAL AND SCROTAL AREA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
FUNGAL SKIN INFECTION - LEFT SHIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GALL STONES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GALLSTONES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GASTRIC IRRITATION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GASTROENERITIS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GASTROENTERITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
GASTROINTESTINAL SYMPTOMS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
GASTROINTESTINAL UPSET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GASTROINTESTINAL VIRAL INFECTION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GENERAL BODY ACHES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GENERAL MALAISE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
GENERAL MALISE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GENERAL WEAKNESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GENERALISED ACHES AND PAINS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GENERALISED BODY ACHING - MUSCULAR			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GENERALISED BODY RASH			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GENERALISED ITCH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GENERALISED PRURITIS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	2	0
GENERALISED RASH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GENERALISED SKIN RASH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
GI URGENCY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GLOSSAL SWELLING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
GOUT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
GOUT IN FINGERS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GOUT IN LEFT ANKLE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
GRADE 1 MYALGIA, GENERALLY AFFECTING LEGS AND HIP AREAS.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GRADE 2 TRANSAMINITIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1

GRADE 3 HAEM TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
GRADE 3 NEUTS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
GRADE 3 TOXICITY AST/ALT RESULTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GRADE 3 TOXICITY PLATLETS AND NEUTROPHILS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GRADE 3 TOXICITY, NEUTROPHILS 0.3			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GRIPEY ABDOMINAL PAINS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
GRITTINESS AND DISCHARGE FROM EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GRITTY EYES			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
GRITTY SKIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
GUM DISEASE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HAEM TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	3	0
HAEM TOXICITY - LOW PLATELATES - PROLONGED MENSES			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HAEM TOXICITY PLATELETS GRADE 2 TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HAEMATEMESIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMATOLOGICAL TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	0 / 107 (0.00%)
occurrences (all)	0	3	0
HAEMATOLOGICAL TOXICITY THROMBOCYTOPAENIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMATOLOGICAL TOXICITY WITH A NEUTROPHIL COUNT OF 0.8			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMATOLOGICAL TOXICITY. PLATELETS 46			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMATOMA FOLLOWING BONE MARROW			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HAEMATUREA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HAEMATURIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMATURIA (URINE)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMOGLOBIN 80			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMOPTYSIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HAEMORRHOIDS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HAIR LOSS			
subjects affected / exposed	2 / 89 (2.25%)	2 / 62 (3.23%)	0 / 107 (0.00%)
occurrences (all)	2	2	0
HAIR THINNING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
HALLUCINATIONS FOLLOWING INTERFERON INJECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HEAD PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HEADACHE			
subjects affected / exposed	1 / 89 (1.12%)	2 / 62 (3.23%)	6 / 107 (5.61%)
occurrences (all)	2	2	8
HEADACHES			
subjects affected / exposed	7 / 89 (7.87%)	2 / 62 (3.23%)	5 / 107 (4.67%)
occurrences (all)	7	2	6
HEADACHES (OCCASIONAL)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HEADACHES AND ACHES AND PAINS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HEARING LOSS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1

HEARTBURN			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	2	0	2
HEAVY PERIODS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HEPATIC - RAISED GGT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HEPATOTOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HERPES SIMPLEX INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HIATUS HERNIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HOT AND COLD EPISODES RECENTLY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HOT FLUSHES			
subjects affected / exposed	1 / 89 (1.12%)	3 / 62 (4.84%)	0 / 107 (0.00%)
occurrences (all)	1	3	0
HOT FLUSHES/SWEATS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HYDROCELE/ PLICATION OF HYDROCELE SAC			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HYPERBILIRUBINAEMIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HYPERCHOLESTEREAMIA			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
HYPERSENSITIVE SKIN REACTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
HYPERTENSION			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	2	0	2
HYPOCALCAEMIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
HYPOKALEMIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HYPOTHYROIDISM			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
HYSTERECTOMY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INCREASE SWEATS, DAY AND NIGHT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INCREASED FATIGUE			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
INCREASED MUSCLE WEAKNESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INDIGESTION			
subjects affected / exposed	3 / 89 (3.37%)	0 / 62 (0.00%)	10 / 107 (9.35%)
occurrences (all)	4	0	12
INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INFECTION (CHEST)			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INFECTION - VAGINAL THRUSH			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INFECTION WITH GRADE 1 NEUTROPHILS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INFECTION WITH NORMAL ANC			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INFECTION- BLADDER (URINARY TRACT)			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	3	0
INFLAMMED AND SWOLLEN EYELIDS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INFLAMMED FACE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INFLAMMED RIGHT AND LEFT AXILLA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INFLUENZA			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	2	0	1
INJURY TO RIGHT ELBOW			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INSOMNIA			
subjects affected / exposed	3 / 89 (3.37%)	3 / 62 (4.84%)	5 / 107 (4.67%)
occurrences (all)	5	3	5
INSPIRATORY CREPITATIONS			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INTERMITTANT CRAMPS IN VARIOUS PARTS OF BODY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INTERMITTANT DIARRHOEA, UNKNOWN ONSET DATE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INTERMITTANT HEADACHES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INTERMITTENT BURNIG SENSATION ON BACK OF HANDS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INTERMITTENT CENTRAL AND LEFT SIDED CHEST PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INTERMITTENT CRAMPS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
INTERMITTENT CRAMPS IN JOINTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INTERMITTENT DIARRHOEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
INTERMITTENT HOT FLUSHES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
INTERMITTENT MUSCLE CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INTERMITTENT NAUSEA			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
INTERMITTENT VOMITING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
INTERMITTENT VOMITING, MAINLY MORNING.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
IRON DEFICIENCY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
IRON DEFICIENT ANAEMIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
IRREGULAR HEART BEAT - ECG AND ECHO NAD			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
IRRITABLE BOWEL			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
IRRITATION RIGHT EAR			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ITCHING BACK			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ITCHING IN LEFT FOOT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ITCHING OVER THE SCALP AND LEFT LEG. ASSOCIATED WITH DRY SKIN			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ITCHING,ERYTHEMATOUS LOWER BACK, ARMS AND LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ITCHY PIMPLES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ITCHY RASH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ITCHY RASH ON LEGS , FACE AND EARLOBES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ITCHY SKIN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ITCHY SKIN, DRY AND RED			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ITCHY SPOTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ITCHY, RED SKIN, RASH VISIBLE ON ARMS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
ITCY RASH ACROSS CHEST			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
JAUNDICE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
JOINT ACHE			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
JOINT PAIN			
subjects affected / exposed	3 / 89 (3.37%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	3	0	2
JOINT PAIN (ARTHRALGIA)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
JOINT PAIN R HIP, GROIN AND SHOULDER			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
JOINT PAINS			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
JOINT SWELLING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
KERATOACANTHOMAS (ONE SPOT ABOVE LIP)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
KNEE PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LAMINAR MACULAR HOLE LEFT EYE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LARGE BRUISE TO CHEST			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LEFT EYE SUBCONJUNCTIVAL HAEMORRHAGE.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LEFT GROIN AND HIP PAIN			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LEFT GROIN PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEFT KNEES AND FEET ACHE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LEFT LEG PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LEFT LEG SWELLING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEFT RETINAL DETACHMENT. REPAIRED SURGICALLY ON 5/09/2012.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEFT SHOULDER NERVE PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEFT SHOULDER PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LEFT UPPER QUADRANT DISCOMFORT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LEFT UPPER QUADRANT PAIN			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
LEG ACHE, ESPECIALLY IN KNEES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEG AND ARM CRAMPS			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEG CRAMPS			
subjects affected / exposed	7 / 89 (7.87%)	1 / 62 (1.61%)	6 / 107 (5.61%)
occurrences (all)	7	1	6
LEG CRAMPS (ON AND OFF) WHEN DRUGS COMMENCED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEG CRAMPS,			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEG OEDEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LEG PAIN - SEVERE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEG SWELLING			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LEGACHE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LEGS ACHE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LETHAGY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LETHARGY			
subjects affected / exposed	3 / 89 (3.37%)	3 / 62 (4.84%)	6 / 107 (5.61%)
occurrences (all)	3	4	7
LETHARGY, MALAISE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1

LETHERGY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LETHERGY/TIREDNESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LEUCOPENIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LEUKOPENIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LIGHT HEADED			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
LIGHT HEADED AND UNABLE TO TALK FOR 30 SES. NO TRUE LOC. BACK TO NORMAL WITHIN 2 MINS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LIGHTHEADED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LIGHTHEADEDNESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LIP SWELLING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LIP SWELLING AND TONGUE TIGHTENING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOCAL SKIN REACTION - REDNESS AND SLIGHT SWELLING AT INJECTION SITES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LONG MONTHLY PERIODS			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LOOSE BOWEL MOTIONS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOOSE MOTIONS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOOSE STOOL			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOOSE STOOLS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	2 / 107 (1.87%)
occurrences (all)	0	1	2
LOSS OF FEELING AND FUNCTION OF HIS RIGHT HAND			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOSS OF APPETITE			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	2 / 107 (1.87%)
occurrences (all)	1	1	2
LOSS OF TASTE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOW BACK AND LEG PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOW BACK PAIN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	2	1
LOW HAEMOGLOBIN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	2
LOW MOOD			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	2	0	2

LOW NEUTROPHIL COUNT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOW NEUTROPHIL COUNT. 0.94 X 10*9/L. GRADE 3 TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
LOW NEUTROPHILS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
LOW NEUTRPOHILS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOW PLATELET COUNT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOW PLATELETS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOW PLATLET COUNT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOW SERUM VITAMEN D LEVELS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOW STERNUM XIPHISTERNAL NIGGLE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOW WHITE CELL COUNT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
LOWER ABDOMINAL PAIN. ? IRRITABLE BOWEL.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOWER BACK PAIN RADIATING DOWN BOTH LEGS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOWER EYELID PUFFINESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
LOWER LUBAR SPINE MUSCULAR PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MACROSCOPIC HAEMATURIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MACULAR RASH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MACULAR RASH - TRUNK AND ARMS.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MACULAR RASH ON BODY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MACULAR RASH ON FACE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MACULOPAPULAR RASH ON LEFT FOOT AND CHEST			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MALAENA (REGULAR BOUTS)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MALAENA STOOLS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MELTALIC TASTE IN MOUTH			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MENORRHAGIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
METALLIC TASTE IN MOUTH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MIGRAINE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MIGRAINE AFTER HAVING INTERFERON			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MIGRAINES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MILD ANKLE ODEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MILD BILATERAL PITTING OEDEMA TO THE ANKLES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MILD CRAMPS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MILD DEPRESSION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MILD OEDEMA AROUND LEFT EYE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MILD PERIORBITAL OEDEMA			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MILD PITTING OEDEMA IN BOTH ANKLES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MODERATE PITTING OEDEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MOIST EYES-SLIGHHT SWELLING ON EYE BALLS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MOOD ALTERATION			
subjects affected / exposed	0 / 89 (0.00%)	2 / 62 (3.23%)	0 / 107 (0.00%)
occurrences (all)	0	2	0
MOOD ALTERATION / DEPRESSION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MOOD ALTERATION-DEPRESSION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MOOD IS VERY LOW AND NOT AS IT WAS.			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MOOD SWINGS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
MOOD SWINGS, DEPRESSION, FEELING TIRED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MOUTH DRYNESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MOUTH ULCER			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MOUTH ULCERS			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	3 / 107 (2.80%)
occurrences (all)	2	0	3
MUCOSITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MULTIPLE WART LIKE GROWTHS ON BACK			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MUSCLE ACHE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MUSCLE ACHES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE ACHES/PAINS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE CRAMP			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE CRAMPING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MUSCLE CRAMPS			
subjects affected / exposed	7 / 89 (7.87%)	3 / 62 (4.84%)	1 / 107 (0.93%)
occurrences (all)	7	3	1
MUSCLE CRAMPS ALL OVER BODY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MUSCLE CRAMPS IN LEGS AND HANDS			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MUSCLE CRAMPS/JOINT PAINS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE PAIN (LEGS)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE PAIN - KNEES AND LOWER LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE PAINS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE SPASMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MUSCLE SPASMS OF BOTH LEGS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MUSCLE STRAIN TO LEFT FOREARM, THIGH AND CALF			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCLE WEAKNESS AND PAINS IN ARMS, HANDS AND SHOULDERS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MUSCLOSKELETAL EVENT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MUSCULAR CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MUSCULAR PAIN			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MUSCULOSKELETAL BONE PAIN IN RIBS TO CLAVICALS AND NECK TO MID-THORACIC LEVEL)			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
MUSCULOSKELETAL PAIN/ CRAMPING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MYALGIA			
subjects affected / exposed	4 / 89 (4.49%)	3 / 62 (4.84%)	8 / 107 (7.48%)
occurrences (all)	4	3	8
MYALGIA /BONE PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
MYALGIA PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
MYALGIA/ARTHRALGIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NAUSA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	19 / 89 (21.35%)	12 / 62 (19.35%)	35 / 107 (32.71%)
occurrences (all)	28	14	51
NAUSEA (POST IMATINIB DOSE)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NAUSEA AND DIARRHOEA			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NAUSEA AND DISSINESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NAUSEA AND LOSS OF APPETITE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NAUSEA AND SICKNESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NAUSEA AND VOMITING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	1	0	3
NAUSEA AND VOMITTING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NAUSEA VOMITED ONCE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NAUSEA WITH ONE EPISODE OF VOMITTING AT HOME			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NAUSEA, LOOSE STOOLS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NEUROTOXICITY HANDS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NEUTROPAENIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NEUTROPAENIC. NEUTROPHIL COUNT 0.8			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NEUTROPENIA			
subjects affected / exposed	10 / 89 (11.24%)	19 / 62 (30.65%)	9 / 107 (8.41%)
occurrences (all)	20	37	15
NEUTROPENIA AND LEUCOPENIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NEUTROPENIA ONLY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NEUTROPENIA. 0.86X10*9/L. GRADE 3 TOXICITY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NEUTROPENIA. NEUTROPHILS 0.9 27/08/2008			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NEUTROPENIC			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NEUTROPHILS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NEUTROPHILS 0.9			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NIGHT CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NIGHT LEG CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NIGHT SWEAT			

subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
NIGHT SWEATS			
subjects affected / exposed	4 / 89 (4.49%)	2 / 62 (3.23%)	2 / 107 (1.87%)
occurrences (all)	4	3	2
NIGHTMARES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NIGHTMARES/ SLEEP DISTURBANCE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NIGHTSWEATS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NIPPLE TENDERNESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NOCTERNAL COUGH/WHEEZE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NOCTURNAL CRAMP			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NOCTURNAL CRAMPS IN CALVES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
NON- HAEM TOXICITY, HEPATIC ALT RAISED			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NON-HAEMATOLOGICAL (JOINT PAINS)			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
NONE			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NOSE BLEED			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	2	0	1
NOSE BLEEDS X4			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NOSEBLEED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NUMBNESS IN RIGHT THIGH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
NUMBNESS TO RIGHT BIG TOE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OCC HEADACHES RETURNED			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
OCCAISONAL NON SPECIFIC INFECTIVE SYMPTOM			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OCCASIONAL BRIEF TINGLING IN ARMS AND BRIEF SHARP PAINS IN BACK LASTING 2-3 MINS ONLY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OCCASIONAL BRUISING OVER BODY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OCCASIONAL CRAMPS			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
OCCASIONAL CRAMPS IN HANDS			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OCCASIONAL DIARRHOEA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OCCASIONAL GASTROINTESTINAL DISTURBANCE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OCCASIONAL HEADACHE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
OCCASIONAL NAUSEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OCCASSIONAL CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OCCULAR / OTHER - PERI-ORBITAL OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OCULAR			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
OEDEMA BENEATH BOTH EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OEDEMA IN EYELIDS AND LOWER LIMBS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OEDEMA OF ANKLES, FEET, FINGERS, FACE AND EYELIDS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OEDEMA OF EYE LIDS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OEDEMA OF LEGS AND FEET PERSISTS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
OEDEMA/FLUID RETENTION.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OEDEMA: HEAD & NECK			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OLECRANON BURSITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ON PHYSICAL EXAMINATION CONSULTANT NOTED SPLENOMEGALY TO BE 2-3 CM			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
OPTHALMIC ZOSTER			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ORAL THRUSH			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
ORBITAL OEDEMA			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
OTITIS EXTERNA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
P R BLEEDING - ? HAEMORRHOID			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN (HIP)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN - CARDIAC			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
PAIN - EXTREMITY-LIMB (NIGHT CRAMPS)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN - MUSCLE (MYALGIA)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN - STOMACH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN ABDOMINAL NOS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN FOLLOWING BONE MARROW TEST MAKING WALKING DIFFICULT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAIN IN ANKLE COMES AND GOES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAIN IN ARMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN IN BACK FOLLOWING INTERFERON INJECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAIN IN BACK OF LEG			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN IN BOTH LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN IN BUTTUCK POST BONE MARROW ASPIRATION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN IN JAW AND TEETH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN IN LEFT FOOT (SCREW INSITU CAUSING PAIN)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN IN LEFT FOOT.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN IN LEG, LEFT CALF			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAIN IN LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
PAIN IN LOWER LIMBS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN IN RIGHT BIG TOE PA ATHRALGIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAIN IN SHINS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN IN TEETH			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN IN THIGHS/ARMS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN IN WRIST			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN LEFT SIDE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN LEFT UPPER QUADRANT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN ON DEFAECATION/SOME BLEEDING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN RIGHT BIG TOE (NOT ACUTE GOUT)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN TO BASE OF RIGHT BIG TOE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN TO KNEES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN TO LOWER BACK			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAIN TO SPLEEN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
PAIN, BASE OF SKULL DOWN TO NECK			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN, SHOULDER AND BACK			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN- ABDOMEN			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAIN- JOINTS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN-EXTREMITIES-LIMB			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN-LOWER BACK AND BOTH UPPER THIGHS.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAIN-RIGHT UPPER QUADRANT, ? GALLSTONES, ULTRASOUND NORMAL			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAIN/TENDERNESS SCALP			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAINFUL ARTHRITIS IN ELBOWS HEELS ANKLES			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAINFUL CRAMPS IN HANDS AND LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAINFUL FEET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAINFUL HIPS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAINFUL KNEES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAINFUL RIBS LEFT SIDE AFTER A FALL			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAINFUL RIGHT EYE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAINFUL RIGHT KNEE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAINFUL RIGHT SHOULDER			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAINFUL SPOT IN RIGHT EAR			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAINFUL, ACHING JOINTS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PAINFUL, BLISTERING LESIONS ON LEGS & FEET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAINS IN BODY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	4
PAINS IN CALFS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PAINS IN LEGS			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PAINS IN LOWER LIMBS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
PALPITATIONS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
PARASTHESIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PARKINSON'S DISEASE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PASSED BLACK WATERY STOOLS, VOMITING WITH SOME BLOOD PRESENT			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PASSING BLOOD ASSOCIATED WITH LOWER ABDOMINAL PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PEELING SKIN ON HANDS AND FEET			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PERI ANAL ITCHING			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PERI ORBITAL OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	3 / 107 (2.80%)
occurrences (all)	0	0	4
PERI-ORBITAL ODEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PERI-ORBITAL OEDEMA			

subjects affected / exposed	4 / 89 (4.49%)	1 / 62 (1.61%)	5 / 107 (4.67%)
occurrences (all)	4	1	6
PERI-ORBITAL OEMEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PERIOBITAL OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
PERIOD PAINS, HEAD ACHE AND BACK PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PERIODIC CRAMP			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PERIODIC SWEATING			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PERIORBIATAL OEDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PERIORBITAL EDEMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PERIORBITAL ODEMA			
subjects affected / exposed	3 / 89 (3.37%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	3	0	0
PERIORBITAL OEDEMA			
subjects affected / exposed	6 / 89 (6.74%)	3 / 62 (4.84%)	13 / 107 (12.15%)
occurrences (all)	6	3	14
PERIORBITAL OEDEMA IN THE MORNING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PERIORBITAL OEDEMA UPPER EYELIDS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PERIORBITAL PUFFINESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PERIORBITAL SWELLING			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	0	1	1
PERIORIBITAL OEDEMA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PERIPHERAL NEUROPATHY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PERIPHERAL OEDEMA			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	1	1	1
PERSISTANT DIARRHOEA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PERSISTANT NAUSEA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PERSISTENT UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PETECHIAL RASH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PIGMENTATION CHANGES. VITILIGO			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PINS AND NEDDLES FEELING IN LEFT ARM			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PINS AND NEEDLES TO HANDS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PLANTAR FASCIITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PLATELETS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
PLEURAL EFFUSION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	2
PLEURITIC CHEST PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
POOR APPETITE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
POOR APPPETITE + LOSS OF TASTE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
POSSIBLE URINARY TRACT INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
POSTERIOR UVEITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PR BLEEDING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PR BLEEDING - HAEMORRHOIDS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0

PRIMARY OPEN ANGLE GLAUCOMA BOTH EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	2	0	1
PROSTATITIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PRURITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
PRURITUS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PSYCHOLOGICALLY UNWELL-NO DIAGNOSIS AVAILABLE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PUFFINESS AROUND EYES			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	1	1	1
PUFFINESS AROUND EYES AND FACE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PUFFINESS OF THE EYES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PUFFY ANKLES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PUFFY EYES			
subjects affected / exposed	3 / 89 (3.37%)	2 / 62 (3.23%)	9 / 107 (8.41%)
occurrences (all)	3	3	10
PUFFY FACE AND EYES			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
PUFFY FACE IN THE MORNING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PUFFY SORE EYES (DRY)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PURITIS/RASH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
PYREXIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
PYREXIA/ RIGOR			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RAISED ALP			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RAISED ALT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RAISED ALT 200 U/L			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RAISED BILIRUBIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RAISED SERUM PROTEIN METABOLIC LABORATORY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RAS,H INFLAMMED FOLLICLES OVER BOTH SCFS			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RASH			
subjects affected / exposed	6 / 89 (6.74%)	4 / 62 (6.45%)	10 / 107 (9.35%)
occurrences (all)	6	5	13
RASH ALL OVER BODY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH AROUND OLD TATOOS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH BACK OF NECK			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RASH NECK AND ELBOW			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH ON ARMS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH ON ARMS AND LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
RASH ON ARMS, LEGS AND BACK			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RASH ON BODY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	2 / 107 (1.87%)
occurrences (all)	0	1	2
RASH ON CHEST			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH ON CHEST AND ABDOMEN			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH ON FACE AND LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH ON FACE, CHEST AND ARMS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH ON LEGS/ HANDS/FEET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH ON SHIN AND RASH IN NATAL CLEFT-ITCHY AND ERYTHEMATOUS, NO SKIN BREAKDOWN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH OVER 50% OF BODY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH OVER WHOLE BODY. NO PRURITIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH RIGHT ARM			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RASH RIGHT SIDE OF NECK			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RASH TO FACE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RASH, ITCHY ARMS AND LEGS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RASH-UNSPECIFIED LOCATION AND TYPE			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RECOVERING PSORIASIS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RED ITCHY LESIONS ON BODY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RED LEFT EYE- GIVEN CHLORAMPHENICOL BY GP			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RED SORE GRITTY EYES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RED SPOTS ON BOTH LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RED SWELLING IN NAIL BED OF RIGHT INDEX FINGER			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RED, ITCHY RASH OVER WHOLE BODY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
REDNESS IN EYES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
REDUCED APPETITE			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
REDUCED REFLEXES ON LEFT AT KNEE TO ANKLE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
REDUCED URINARY FLOW			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
REDUNDANT PREPUCE/PHIMOSIS NOS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
REMOVAL OF UTERINE FIBROIDS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
REPEATED FALLS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RESPIRATORY TRACT INFECTION.			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RESPIRATORY VIRUS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RIB PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RIGHT EYE HAEMORRHAGE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RIGHT HAND INTERMITTANT CRAMPS/SPASMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RIGHT QUADRANT DISCOMFORT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RIGHT SIDE UPPER CHEST PAIN			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
RIGHT SIDED CHEST PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RIGHT SIDED NEURALGIA PAIN IN HEAD			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RIGORS AND CHILLS - NO SOURCE OF INFECTION IDENTIFIED.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
RIGORS/CHILLS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
RISING ALKALINE PHOSPHATASE LEVELS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ROSACEA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	2
SCROTAL CYST			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SCIATICA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SEBACECUS CYSTS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SENSITIVE FACIAL SKIN/HAIR WHEN SHAVING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SENSITIVE TEETH			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SENSORY NEUROPATHY IN FEET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SENSORY NEUROPATHY IN HANDS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SEVERE BONE PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SEVERE DRY SKIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SEVERE GASTROINTESTINAL TRACT SYMPTOMS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SEVERE HEADACHES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SEVERE NAUSEA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SEVERE SHIN PAIN IN LEGS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SHARP PAINS IN KNEES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SHINGLES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SHIVERY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1

SHIVERY EPISODE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SHORT OF BREATH			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SHORT OF BREATH ON EXERTION			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
SHORTNESS OF BREATH			
subjects affected / exposed	1 / 89 (1.12%)	2 / 62 (3.23%)	2 / 107 (1.87%)
occurrences (all)	1	3	3
SHORTNESS OF BREATH ON EXERTION			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	1	1	1
SHOULDER PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
SICKNESS AND DIZZINESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SIGNIFICANT PERIPHERAL OEDEMA AFFECTING THIGHS WITH ASSOCIATED PAIN IN FEET			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SIGNIFICANT VIRAL LOAD AT 1,260,000IU/ML, HEPATITIS B DNA DETECTED			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SINUS INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SINUS PROBLEMS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SINUSITIS			

subjects affected / exposed	2 / 89 (2.25%)	1 / 62 (1.61%)	2 / 107 (1.87%)
occurrences (all)	2	1	3
SKIN BLOTCHES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SKIN DEPIGMENTATION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SKIN FURUNCLES - RE-DIAGNOSED AS ECZEMA ON 27-FEB-2008 BY CONSULTANT DERMATOLOGIST			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SKIN INFECTION AROUND ANUS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
SKIN LIGHTENING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SKIN MOLES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SKIN RASH			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
SKIN RASH (SHEST AND ARMS)			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SKIN RASH TO FEET			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SKIN REACTION (RASH)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SLEEP DISTURBANCE - VIVID DREAMS			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SLEEPIMG PROBLEMS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SLEEPLESSNESS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SLIGHT COUGH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SLIGHTLY SWOLLEN FACE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SLIGHTLY UPSET TUMMY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SOB ON EXERTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SOFT TISSUE DAMAGE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SOME ALOPECIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SORE AND INFLAMED FORESKIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SORE EARS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SORE EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	3 / 107 (2.80%)
occurrences (all)	0	0	3
SORE HEAD			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SORE MOUTH			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SORE NOSE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SORE NECK			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SORE ON LIP			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SORE PATCHES IN MOUTH			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SORE RIGHT HIP			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SORE SHINS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SORE THROAT			
subjects affected / exposed	2 / 89 (2.25%)	4 / 62 (6.45%)	3 / 107 (2.80%)
occurrences (all)	2	4	3
SORE TONGUE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SORENESS AND INFLAMMATION NIPPLES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SORE WATERY EYES			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0

SOUNDING LIKE A BIT OF NASAL BLOCKAGE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SPLEENIC PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SPLENIC PAIN			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SPONTANEOUS CONJUNCTIVAL BLEED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SPONTANEOUS HAEMATOMA OF RIGHT EYE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SPORADIC VOMITTING EPISODES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SPOTS ON KNEES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
STIFF JOINTS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
STOMACH CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	0	0	2
STOMACH TENDERNESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
STOMACH UPSET			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
STRAINED BACK MUSCLES			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
STREAMING OF EYES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
STRESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
STRESS RELATED HEADACHES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
STUFFY NOSE (NASAL POLYPS)			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SUB CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SUB CONJUNTIVAL HAEMATOMA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SUB CONJUNTIVAL HAEMORRHAGE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SUB-CONJUNCTIVAL HAEMORRHAGE LEFT EYE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SUBCONJUNCTIVAL HAEMHORRAGE IN LEFT EYE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SUBCONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	1	0	1
SUPERFICIAL BLEEDING AFTER PASSING STOOL			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SUPERFICIAL WOUND INFECTION FROM PERITONIAL CATHETER INSERTION			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SWEATING			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	3 / 107 (2.80%)
occurrences (all)	0	0	3
SWEATS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SWEATY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SWELLING AND INDURATION AT INJECTION SITE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SWELLING MOSTLY AROUND EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SWELLING OF LEFT FOOT			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SWOLLEN AIRWAY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SWOLLEN ANKLES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SWOLLEN ARMS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SWOLLEN EYES			

subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	1	1	0
SWOLLEN EYES - FEELS LIKE A COLD. CHESTY BUT NON PRODUCTIVE COUGH.			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SWOLLEN FACE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SWOLLEN GUMS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
SWOLLEN LEGS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SWOLLEN PAINFUL RIGHT LEG			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SWOLLEN RIGHT INDEX FINGER			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
SWOLLEN TONGUE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SYMPTOMATIC ANAEMIA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
SYNCOPE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
TACHYCARDIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TASTE ALTERATION			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TEETH AND JAWS - DULL ACHE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
TEMPERATURE AND SHORTNESS OF BREATH			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
TENDER HARD AREA ANTERIOR ASPECT RIGHT THIGH			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
TENDER LEFT FOOT			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TENDER NIPPLES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
TENDON CRAMPS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
THINNING HAIR			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
THROAT INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	3 / 107 (2.80%)
occurrences (all)	0	0	3
THROMBOCYTOPAENIA			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	2 / 107 (1.87%)
occurrences (all)	1	0	3
THROMBOCYTOPENIA			
subjects affected / exposed	5 / 89 (5.62%)	8 / 62 (12.90%)	13 / 107 (12.15%)
occurrences (all)	15	20	17
THROMBOCYTOPENIA GRADE 3			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
THROMBOCYTOPENIA-PLATELETS OF 40			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
THROMBOCYTOPENIC			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
THROMBOCYTOPNIA			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
THROMBOYTOPENIA			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	2 / 107 (1.87%)
occurrences (all)	2	1	2
THROMBOYCTOPENIA			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	1 / 107 (0.93%)
occurrences (all)	1	1	1
TINGLING IN LEFT FOEFINGER AND NUMBNESS IN LEFT ARM			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TINGLING TO ENDS OF FINGERS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TINNITUS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
TIRED			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
TIRED AND ACHY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
TIREDNESS			

subjects affected / exposed	3 / 89 (3.37%)	3 / 62 (4.84%)	3 / 107 (2.80%)
occurrences (all)	3	3	3
TIREDNESS/LETHARGY			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TONSILITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
TONSILLECTOMY			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
TONSILLITIS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
TOOTH ABSCESS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
TOOTH EXTRACTION			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TOOTHACHE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TRANSIENT HEADACHE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
TRANSIENT LIGHT HEADACHES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
TYPE II DIABETES			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
ULCERATED UVULA			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
ULCERS ON LOWER LIP			

subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
UNCONTROLLABLE BONE AND MUSCLE PAIN			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
UNWELL, PAIN IN BACK AND ARMS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	2	0
UPPER RESPIRATORY - OTHER			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
UPPER RESPIRATORY CHEST INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	3 / 89 (3.37%)	2 / 62 (3.23%)	1 / 107 (0.93%)
occurrences (all)	4	3	1
UPSET STOMACH (NAUSEA AND DIARRHOEA)			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
URINARY INCONTINENCE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
URINARY INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
URINARY TRACT INFECTION			
subjects affected / exposed	2 / 89 (2.25%)	1 / 62 (1.61%)	4 / 107 (3.74%)
occurrences (all)	2	1	4
URINE FREQUENCY			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
VAGINAL AND PERIANAL THRUSH			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
VAGINAL PROLAPSE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
VAGINAL ULCER			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
VENTRICULAR EPTOPIC BEATS AND ISOLATED SUPRAVENTRICULAR ECTOPICS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
VERTIGO			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
VERY DRY MOUTH CAUSING COUGH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
VIRAL FLU			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
VIRAL GASTROENTERITIS			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
VIRAL ILLNESS (FEVER, COUGH, SORE THROAT)			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
VIRAL INFECTION			
subjects affected / exposed	2 / 89 (2.25%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	2	0	0
VIRUS INFECTION			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
VITAMIN B12 DEFICIENCY			

subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
VITELIGO			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
VITREOUS HAEMORRHAGE			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
VOMITED X1			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
VOMITING			
subjects affected / exposed	3 / 89 (3.37%)	2 / 62 (3.23%)	14 / 107 (13.08%)
occurrences (all)	3	2	18
VOMITING IF EATS OR DRINKS CERTAIN FOOD STUFFS			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
VOMITTING			
subjects affected / exposed	1 / 89 (1.12%)	1 / 62 (1.61%)	3 / 107 (2.80%)
occurrences (all)	2	1	4
VOMMITING			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
WASHED OUT EPISODE			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
WASP STING			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
WATERING EYES			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
WATERY EYES			
subjects affected / exposed	2 / 89 (2.25%)	2 / 62 (3.23%)	1 / 107 (0.93%)
occurrences (all)	2	2	1

WATERY EYES (ON AND OFF) WHEN DRUGS COMMENCED			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
WATERY EYES WITH SOME STICKINESS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
WATERY EYES, ESPECIALLY FIRST THING IN THE MORNING.			
subjects affected / exposed	1 / 89 (1.12%)	0 / 62 (0.00%)	0 / 107 (0.00%)
occurrences (all)	1	0	0
WATERY/WEEPING LEFT EYE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
WBC 2.91, NEUTS 1.17			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
WEAKNESS IN LEGS			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
WEIGHT GAIN			
subjects affected / exposed	6 / 89 (6.74%)	3 / 62 (4.84%)	3 / 107 (2.80%)
occurrences (all)	11	8	4
WEIGHT LOSS			
subjects affected / exposed	3 / 89 (3.37%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	3	1	0
WEIGHT LOSS (DUE TO VOMITING)			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
WHEEZING OVER CHEST			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
WIDESPREAD ERYTHEMATOUS CONFLUENT MACULAR RASH			
subjects affected / exposed	0 / 89 (0.00%)	1 / 62 (1.61%)	0 / 107 (0.00%)
occurrences (all)	0	1	0
WIDESPREAD RASH			

subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1
WORSENING FATIGUE			
subjects affected / exposed	0 / 89 (0.00%)	0 / 62 (0.00%)	1 / 107 (0.93%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 July 2006	The protocol was amended to adjust the dosing schedule for pegylated interferon alpha in one of the treatment arms following reports of tolerability issues from the first patients randomised to the arm. Other administrative changes were also made plus some definitions added following the introduction of the European Clinical Trials Directive.
08 January 2007	The amendment covered changes in the Patient Information Leaflet (PIL) and Informed Consent Form (IC) to reflect the changes in Protocol Amendment 1, Protocol version 15 recently approved by MREC. The protocol amendment concerned adjustment of the dosing schedule for pegylated interferon alpha in one of the treatment arms following reports of tolerability issues from the first patients randomised to the arm. The amended patient information leaflet reflects the new starting dose of 90ug interferon every 4 weeks. Also new documents to help patients take their medication were created and approved.
17 October 2007	The main purpose of this amendment to the protocol and PIL/IC was to close recruitment into the combination treatment arm (Arm C). The protocol was previously amended to adjust the dosing schedule in Arm C following reports of tolerability issues from the first patients randomised to the arm. The amendment to the dosing schedule resulted in fewer reports of toxicities but continued to be an issue for some patients. The perception of toxicity and the route of administration of the pegylated interferon (SC injection) led to Arm C being very unpopular with both clinicians and patients. This prevented the uptake of the study at some sites and severely hampered recruitment at active sites. It was considered a high risk of the trial failing to recruit if randomisation into Arm C continued any longer.
19 December 2008	This amendment closed the recruitment of patients into the study earlier than anticipated. This was due to several reasons; slow recruitment, the publication of data from another study which showed that there was no statistical difference in response rates between 2 of the arms used in this study, the introduction of 2 new drugs for CML onto the market and the advent of a new trial, Spirit 2, which would directly compete for the same patient population. Therefore the Study Management Committee recommended the closure of recruitment at all sites by 1st February 2009.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported