



Clinical trial results:

An Open-Label, Multicentre, Single-Arm Study to Characterise the Efficacy, Safety, and Tolerability of Gefitinib 250 mg (IRESSA™1) as First-Line Treatment in Caucasian Patients Who Have Epidermal Growth Factor Receptor (EGFR) Mutation-Positive Locally Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)

Summary

EudraCT number	2005-004548-30
Trial protocol	DK
Global end of trial date	26 June 2015

Results information

Result version number	v1 (current)
This version publication date	25 June 2016
First version publication date	25 June 2016

Trial information

Trial identification

Sponsor protocol code	1839IL/0225
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00229697
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Astra Zeneca
Sponsor organisation address	Mereside Block 11S, Alderley Park, United Kingdom, SK10 4TG
Public contact	Yuri Rukazenzov, Astra Zeneca, +44 1625 231825, yuri.rukazenzov@astrazeneca.com
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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	26 June 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 December 2006
Global end of trial reached?	Yes
Global end of trial date	26 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Patients were stratified into 2 categories based on their prior hormonal therapy. The 2 strata were as follows: 1) Stratum 1- patients with newly diagnosed disease or patients who had completed adjuvant therapy with tamoxifen (Nolvadex) at least 1 year prior to starting this study and 2) Stratum 2 - patients with recurrent disease during, or after adjuvant aromatase inhibitor (AI), or failing first line treatment with an AI for metastatic disease. The primary objectives of the study were:

Stratum 1: To compare the time to progression (TTP) between 2 treatment arms (tamoxifen + gefitinib [IRESSA™] versus tamoxifen + placebo).

Stratum 2: To compare the clinical benefit rate (CBR) between 2 treatment arms (tamoxifen + gefitinib versus tamoxifen + placebo).

Protection of trial subjects:

All patients entered into the study adhered to the inclusion and exclusion criteria and were free to withdraw at any time. Patients were monitored for safety and efficacy throughout the study which was performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and are consistent with ICH/Good Clinical Practice, applicable regulatory requirements and the AstraZeneca policy on Bioethics.

Background therapy:

Nolvadex one 20 mg tablet daily

Evidence for comparator: -

Actual start date of recruitment	14 October 2003
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 23
Country: Number of subjects enrolled	Australia: 25
Country: Number of subjects enrolled	Belgium: 43
Country: Number of subjects enrolled	Brazil: 28
Country: Number of subjects enrolled	Canada: 36
Country: Number of subjects enrolled	Denmark: 2
Country: Number of subjects enrolled	France: 27
Country: Number of subjects enrolled	Germany: 21
Country: Number of subjects enrolled	South Africa: 12
Country: Number of subjects enrolled	Spain: 22
Country: Number of subjects enrolled	United Kingdom: 28
Country: Number of subjects enrolled	United States: 22

Worldwide total number of subjects	289
EEA total number of subjects	143

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)	166
From 65 to 84 years	120
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

First subject was enrolled on 14 October 2003, last subject was enrolled on 30 June 2006

Pre-assignment

Screening details:

All patients must be female; >18 yrs; have WHO PS of 0, 1 or 2; fulfil the inclusion and exclusion criteria, and have histologically confirmed metastatic adenocarcinoma of the breast that is ER and/or PR positive

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Carer, Data analyst, Assessor, Subject

Blinding implementation details:

Tablets and packaging of ZD1839 250 mg and placebo to ZD1839 will be visually identical. Participating patients, medical staff and ancillary medical staff remained blinded as to the assignment of ZD1839 or placebo.

Arms

Are arms mutually exclusive?	Yes
Arm title	Strata 1, Nolvadex + Gefitinib

Arm description:

Nolvadex 20mg + Gefitinib 250mg once daily.

Stratum 1- patients with newly diagnosed disease or patients who had completed adjuvant therapy with tamoxifen (Nolvadex) at least 1 year prior to starting this study

Arm type	Experimental
Investigational medicinal product name	Gefitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

250mg once daily

Arm title	Strata 1, Nolvadex + placebo
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Arm description:

Nolvadex 20mg + placebo once daily.

Stratum 1- patients with newly diagnosed disease or patients who had completed adjuvant therapy with tamoxifen (Nolvadex) at least 1 year prior to starting this study

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

matched placebo

Arm title	Strata 2, Nolvadex + Gefitinib
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Arm description:

Nolvadex 20mg + Gefitinib 250mg once daily.

Stratum 2 - patients with recurrent disease during, or after adjuvant aromatase inhibitor (AI), or failing first line treatment with an AI for metastatic disease.

Arm type	Experimental
Investigational medicinal product name	Gefitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use
Dosage and administration details:	
250mg once daily	
Arm title	Strata 2, Nolvadex + Placebo

Arm description:

Nolvadex 20mg + placebo once daily.

Stratum 2 - patients with recurrent disease during, or after adjuvant aromatase inhibitor (AI), or failing first line treatment with an AI for metastatic disease.

Arm type	Placebo
Investigational medicinal product name	placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

matched placebo

Number of subjects in period 1	Strata 1, Nolvadex + Gefitinib	Strata 1, Nolvadex + placebo	Strata 2, Nolvadex + Gefitinib
Started	105	101	48
Completed	98	94	41
Not completed	7	7	7
not recorded	1	2	3
Consent withdrawn by subject	1	1	2
Eligibility criteria not fulfilled	-	1	1
Adverse Event	5	1	-
Lost to follow-up	-	2	1

Number of subjects in period 1	Strata 2, Nolvadex + Placebo
Started	35
Completed	30
Not completed	5
not recorded	3
Consent withdrawn by subject	-
Eligibility criteria not fulfilled	1
Adverse Event	-
Lost to follow-up	1

Baseline characteristics

Reporting groups

Reporting group title	Strata 1, Nolvadex + Gefitinib
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Reporting group description:

Nolvadex 20mg + Gefitinib 250mg once daily.

Stratum 1- patients with newly diagnosed disease or patients who had completed adjuvant therapy with tamoxifen (Nolvadex) at least 1 year prior to starting this study

Reporting group title	Strata 1, Nolvadex + placebo
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Reporting group description:

Nolvadex 20mg + placebo once daily.

Stratum 1- patients with newly diagnosed disease or patients who had completed adjuvant therapy with tamoxifen (Nolvadex) at least 1 year prior to starting this study

Reporting group title	Strata 2, Nolvadex + Gefitinib
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Reporting group description:

Nolvadex 20mg + Gefitinib 250mg once daily.

Stratum 2 - patients with recurrent disease during, or after adjuvant aromatase inhibitor (AI), or failing first line treatment with an AI for metastatic disease.

Reporting group title	Strata 2, Nolvadex + Placebo
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Reporting group description:

Nolvadex 20mg + placebo once daily.

Stratum 2 - patients with recurrent disease during, or after adjuvant aromatase inhibitor (AI), or failing first line treatment with an AI for metastatic disease.

Reporting group values	Strata 1, Nolvadex + Gefitinib	Strata 1, Nolvadex + placebo	Strata 2, Nolvadex + Gefitinib
Number of subjects	105	101	48
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 (18-65 years)	64	58	30
From 66-84 years	39	42	18
85 years and over	2	1	0
Age Continuous			
Units: years			
arithmetic mean	61	62	62.9
standard deviation	± 11.93	± 11.68	± 8.36
Gender Categorical			
Units: Subjects			
Female	105	101	48
Male	0	0	0
Human Epidermal Growth Factor Receptor 2 (HER2) status			
Units: Subjects			
HER2 Positive	22	15	4
HER2 Negative	83	86	44

Reporting group values	Strata 2, Nolvadex + Placebo	Total	
Number of subjects	35	289	
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 (18-65 years)	14	166	
From 66-84 years	21	120	
85 years and over	0	3	
Age Continuous Units: years			
arithmetic mean	66.3		
standard deviation	± 8.57	-	
Gender Categorical Units: Subjects			
Female	35	289	
Male	0	0	
Human Epidermal Growth Factor Receptor 2 (HER2) status Units: Subjects			
HER2 Positive	2	43	
HER2 Negative	33	246	

Subject analysis sets

Subject analysis set title	Intention-to-treat (ITT)
Subject analysis set type	Intention-to-treat

Subject analysis set description:

All patients that are enrolled and receive study treatment are included in the intention-to-treat (ITT) population. The analysis population for all efficacy outcome variables will be the ITT population.

Reporting group values	Intention-to-treat (ITT)		
Number of subjects	289		
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 (18-65 years)	166		
From 66-84 years	120		

85 years and over	3		
Age Continuous Units: years arithmetic mean standard deviation	62.3 ± 11.02		
Gender Categorical Units: Subjects			
Female Male	289 0		
Human Epidermal Growth Factor Receptor 2 (HER2) status Units: Subjects			
HER2 Positive HER2 Negative			

End points

End points reporting groups

Reporting group title	Strata 1, Nolvadex + Gefitinib
Reporting group description: Nolvadex 20mg + Gefitinib 250mg once daily. Stratum 1- patients with newly diagnosed disease or patients who had completed adjuvant therapy with tamoxifen (Nolvadex) at least 1 year prior to starting this study	
Reporting group title	Strata 1, Nolvadex + placebo
Reporting group description: Nolvadex 20mg + placebo once daily. Stratum 1- patients with newly diagnosed disease or patients who had completed adjuvant therapy with tamoxifen (Nolvadex) at least 1 year prior to starting this study	
Reporting group title	Strata 2, Nolvadex + Gefitinib
Reporting group description: Nolvadex 20mg + Gefitinib 250mg once daily. Stratum 2 - patients with recurrent disease during, or after adjuvant aromatase inhibitor (AI), or failing first line treatment with an AI for metastatic disease.	
Reporting group title	Strata 2, Nolvadex + Placebo
Reporting group description: Nolvadex 20mg + placebo once daily. Stratum 2 - patients with recurrent disease during, or after adjuvant aromatase inhibitor (AI), or failing first line treatment with an AI for metastatic disease.	
Subject analysis set title	Intention-to-treat (ITT)
Subject analysis set type	Intention-to-treat
Subject analysis set description: All patients that are enrolled and receive study treatment are included in the intention-to-treat (ITT) population. The analysis population for all efficacy outcome variables will be the ITT population.	

Primary: Stratum 1: Time to Progression (progressive disease or death) (TTP)

End point title	Stratum 1: Time to Progression (progressive disease or death) (TTP) ^[1]
End point description: Stratum 1: To compare the Time to Progression (time from randomisation to progressive disease or death) between 2 treatment arms	
End point type	Primary
End point timeframe: Tumour assessments to be performed at baseline and then every three months until discontinuation	

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: 2.Time to Progression (TTP) for Stratum 1 is a secondary endpoint. According to Protocol there is no analysis for secondary endpoints

End point values	Strata 1, Nolvadex + Gefitinib	Strata 1, Nolvadex + placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	101		
Units: Days				
median (inter-quartile range (Q1-Q3))	331 (92 to 722)	267 (99 to 549)		

Statistical analyses

Statistical analysis title	Stratum 1: Time to Progression
Statistical analysis description:	
The Cox proportional hazards model was used to estimate the TTP hazard ratio for placebo relative to gefitinib, adjusted for the following baseline factors:• Her2neu expression (positive versus negative)• PgR status (positive versus negative)• WHO performance status (0-1 versus 2)• Visceral metastases (yes versus no)	
Comparison groups	Strata 1, Nolvadex + Gefitinib v Strata 1, Nolvadex + placebo
Number of subjects included in analysis	206
Analysis specification	Pre-specified
Analysis type	superiority ^[2]
P-value	= 0.3141 ^[3]
Method	Regression, Cox
Parameter estimate	Cox proportional hazard
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.69

Notes:

[2] - Stratum 1: Time to Progression (progressive disease or death)

[3] - P-values were presented for illustrative purposes only

Primary: Stratum 2: Clinical Benefit Rate (CBR)

End point title	Stratum 2: Clinical Benefit Rate (CBR) ^[4]
End point description:	
Stratum 2: Clinical Benefit Rate (CBR) is the proportion of patients with either complete response (CR), Partial response (PR) or Stable disease (SD) for more than 24 weeks. Response is measured by RECIST (The Response Evaluation Criteria in Solid Tumours).	
End point type	Primary

End point timeframe:

Tumour assessment carried out at baseline and then every 3 months until discontinuation.

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: 1.Clinical Benefit Rate (CBR) for Stratum 2 is a secondary endpoint. According to Protocol there is no analysis for secondary endpoints.

End point values	Strata 2, Nolvadex + Gefitinib	Strata 2, Nolvadex + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	35		
Units: percentage				
number (not applicable)	29.2	31.4		

Statistical analyses

Statistical analysis title	Stratum 2: Clinical benefit Rate
Statistical analysis description: The proportions of patients who experienced clinical benefit was compared between the tamoxifen + gefitinib and tamoxifen + placebo arms using logistic regression. The model included the following baseline factors:• Her2neu expression (0/1+ versus 2+ versus 3+)• PgR status (positive versus negative)• WHO performance status (0-1 versus 2)• Visceral metastases (yes versus no)	
Comparison groups	Strata 2, Nolvadex + Gefitinib v Strata 2, Nolvadex + Placebo
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5167 ^[5]
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.26
upper limit	1.95

Notes:

[5] - P-values were presented for illustrative purposes only

Secondary: Stratum 1: Clinical Benefit Rate (CBR)

End point title	Stratum 1: Clinical Benefit Rate (CBR) ^[6]
End point description: Stratum 1: Clinical Benefit Rate (CBR) is the proportion of patients with either complete response (CR), Partial response (PR) or Stable disease (SD) for more than 24 weeks. Response is measured by RECIST (The Response Evaluation Criteria in Solid Tumours).	
End point type	Secondary
End point timeframe: Tumour assessment carried out at baseline and then every 3 months until discontinuation.	

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: 1.Clinical Benefit Rate (CBR) for Stratum 1 is a secondary endpoint. According to Protocol there is no analysis for secondary endpoints.

End point values	Strata 1, Nolvadex + Gefitinib	Strata 1, Nolvadex + placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	101		
Units: percentage				
number (not applicable)	50.5	45.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Stratum 2: Time to progression (TTP)

End point title	Stratum 2: Time to progression (TTP) ^[7]
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End point description:

Stratum 1: To compare the Time to Progression (TTP) (time from randomisation to progressive disease or death) between 2 treatment arms

End point type	Secondary
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End point timeframe:

Tumour assessments to be performed at baseline and then every three months until discontinuation

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: 2.Time to Progression (TTP) for Stratum 2 is a secondary endpoint. According to Protocol there is no analysis for secondary endpoints.

End point values	Strata 2, Nolvadex + Gefitinib	Strata 2, Nolvadex + Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	35		
Units: days				
median (inter-quartile range (Q1-Q3))	174 (88 to 338)	214 (90 to 372)		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)
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End point description:

Objective Response Rate (ORR) is the proportion of patients with either complete response (CR) or Partial response (PR). Response is measured by RECIST (The Response Evaluation Criteria in Solid Tumours).

End point type	Secondary
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End point timeframe:

Tumour assessments to be performed at baseline and then every three months until discontinuation

End point timeframe:

Tumour assessments to be performed at baseline and then every three months until discontinuation

End point values	Strata 1, Nolvadex + Gefitinib	Strata 1, Nolvadex + placebo	Strata 2, Nolvadex + Gefitinib	Strata 2, Nolvadex + Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	22 ^[12]	15 ^[13]	4 ^[14]	2 ^[15]
Units: percentage				
number (not applicable)	13.6	6.7	0	0

Notes:

[12] - Number of patients analysed is the number of patients within group who are HER2 positive

[13] - Number of patients analysed is the number of patients within group who are HER2 positive

[14] - Number of patients analysed is the number of patients within group who are HER2 positive

[15] - Number of patients analysed is the number of patients within group who are HER2 positive

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Event data were collected at each visit (ie days 1, 30, 90, 180 and every 3 months; also at discontinuation and 30 days post discontinuation).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	Stratum 1: Tamoxifen + Gefitinib
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Reporting group description:

Tamoxifen 20 mg od + Gefitinib 250 mg od

Reporting group title	Stratum 1: Tamoxifen + Placebo
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Reporting group description:

Tamoxifen 20 mg od + Placebo gefitinib od

Reporting group title	Stratum 2: Tamoxifen + Gefitinib
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Reporting group description:

Tamoxifen 20 mg od + Gefitinib 250 mg od

Reporting group title	Stratum 2: Tamoxifen + Placebo
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Reporting group description:

Tamoxifen 20 mg od + Placebo gefitinib od

Serious adverse events	Stratum 1: Tamoxifen + Gefitinib	Stratum 1: Tamoxifen + Placebo	Stratum 2: Tamoxifen + Gefitinib
Total subjects affected by serious adverse events			
subjects affected / exposed	29 / 105 (27.62%)	16 / 101 (15.84%)	11 / 48 (22.92%)
number of deaths (all causes)	25	24	11
number of deaths resulting from adverse events		1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant Neoplasm Progression			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			

subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (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
Lymphoedema			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral Vascular Disorder			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Lymphadenectomy			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Mastectomy			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Asthenia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
General Physical Health Deterioration			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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

Reproductive system and breast disorders			
Endometrial Hyperplasia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Ovarian Cyst			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Uterine Polyp			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Vaginal Haemorrhage			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pleural Effusion			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
subjects affected / exposed	2 / 105 (1.90%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	1 / 2	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			

subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
Dispnoea			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
Pneumothorax			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Injury, poisoning and procedural complications			
Traumatic Brain Injury			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Humerus Fracture			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
Troatic Vertebral Fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Cardiac Failure			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Ventricular Fibrillation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Cardiac Failure Congestive			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
Miocardial Infarction			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
Nervous system disorders			
Coordination Abnormal			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Neurological Symptom			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Paraparesis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Ischaemia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Febrile Neutropenia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Thrombocytopenia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Ascites			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (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
Colitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Diarrhoea			
subjects affected / exposed	4 / 105 (3.81%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	3 / 5	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gastrointestinal Haemorrhage			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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			
subjects affected / exposed	2 / 105 (1.90%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (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
Pancreatitis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 105 (0.00%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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 Acute			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Renal Failure			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological Fracture			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			

subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (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
Diarrhoea Infectious			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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 Bacterial			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Sepsis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Erysipelas			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Tract Infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			

subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous Abscess			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (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
Hypercalcaemia			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	3 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Stratum 2: Tamoxifen + Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 35 (14.29%)		
number of deaths (all causes)	9		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant Neoplasm Progression			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep Vein Thrombosis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertension			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lymphoedema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral Vascular Disorder			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Lymphadenectomy			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Mastectomy			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General Physical Health Deterioration			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Reproductive system and breast disorders			
Endometrial Hyperplasia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian Cyst			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Uterine Polyp			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vaginal Haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pleural Effusion			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary Embolism			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cough			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dispnoea			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Traumatic Brain Injury			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Humerus Fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Troatic Vertebral Fracture			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Cardiac disorders			
Cardiac Failure			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Ventricular Fibrillation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac Failure Congestive			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Miocardial Infarction			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Coordination Abnormal			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neurological Symptom			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Paraparesis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cerebral Ischaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile Neutropenia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ascites			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal Haemorrhage subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Intestinal Obstruction subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nausea subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders Cholecystitis subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaundice subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Failure Acute			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Failure			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pathological Fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone Pain			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Cellulitis			

subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea Infectious				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower Respiratory Tract Infection Bacterial				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory Tract Infection				
subjects affected / exposed	0 / 35 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				

subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subcutaneous Abscess			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypercalcaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Stratum 1: Tamoxifen + Gefitinib	Stratum 1: Tamoxifen + Placebo	Stratum 2: Tamoxifen + Gefitinib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	105 / 105 (100.00%)	87 / 101 (86.14%)	44 / 48 (91.67%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	3
Uterine Leiomyoma			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Flushing			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	3	0	2
Haematoma			

subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Hot Flush			
subjects affected / exposed	12 / 105 (11.43%)	21 / 101 (20.79%)	3 / 48 (6.25%)
occurrences (all)	12	24	3
Hypertension			
subjects affected / exposed	3 / 105 (2.86%)	2 / 101 (1.98%)	1 / 48 (2.08%)
occurrences (all)	3	2	1
Lymphoedema			
subjects affected / exposed	1 / 105 (0.95%)	4 / 101 (3.96%)	3 / 48 (6.25%)
occurrences (all)	1	4	3
Orthostatic Hypotension			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Pallor			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Phlebitis			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Phlebitis Superficial			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Varicose Vein			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Venous Insufficiency			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Preventive Surgery			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	4 / 105 (3.81%)	3 / 101 (2.97%)	6 / 48 (12.50%)
occurrences (all)	4	3	7
Chest Discomfort			
subjects affected / exposed	2 / 105 (1.90%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	4	1	0
Chills			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	17 / 105 (16.19%)	18 / 101 (17.82%)	6 / 48 (12.50%)
occurrences (all)	19	23	7
General Physical Health Deterioration			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Influenza Like Illness			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Mucosal Dryness			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	1	0	2
Mucosal Imflammation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Oedema			
subjects affected / exposed	3 / 105 (2.86%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	4	1	0
Oedema Peripheral			
subjects affected / exposed	4 / 105 (3.81%)	5 / 101 (4.95%)	3 / 48 (6.25%)
occurrences (all)	5	5	4
Pain			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0

Pirexia			
subjects affected / exposed	4 / 105 (3.81%)	2 / 101 (1.98%)	3 / 48 (6.25%)
occurrences (all)	4	2	4
Adverse Drug Reaction			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Chest Pain			
subjects affected / exposed	0 / 105 (0.00%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Face Oedema			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Local Swelling			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Mucosal Haemorrhage			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Seasonal Allergy			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Allergy To Plants			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Breast Inflammation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Breast Pain			

subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Cystocele			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Dyspareunia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Genital Rash			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Pelvic Pain			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Vaginal Discharge			
subjects affected / exposed	4 / 105 (3.81%)	4 / 101 (3.96%)	0 / 48 (0.00%)
occurrences (all)	4	4	0
Vulval Erythema			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal Pruritus			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	1	1	1
Genital Discharge			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Vaginal Haemorrhage			
subjects affected / exposed	0 / 105 (0.00%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Uterine Polyp			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Metrorrhagia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
Vulvovaginal Dryness			

subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
Dysmenorrhoea			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Pruritus Genital			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	3	1	0
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	8 / 105 (7.62%)	5 / 101 (4.95%)	2 / 48 (4.17%)
occurrences (all)	9	5	2
Dispnoea			
subjects affected / exposed	11 / 105 (10.48%)	10 / 101 (9.90%)	4 / 48 (8.33%)
occurrences (all)	16	11	5
Dispnoea Exertional			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	4	0	1
Epistaxis			
subjects affected / exposed	5 / 105 (4.76%)	0 / 101 (0.00%)	4 / 48 (8.33%)
occurrences (all)	6	0	5
Lung Infiltration			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Nasal Congestion			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Nasal Dryness			

subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
Nasal Imflammation			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Nasal Mucosal Disorder			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Pharyngolaryngeal Pain			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	3	0	2
Pleural Effusion			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	4	0	2
Productive Cough			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Pulmonary Congestion			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Rhinitis Allergic			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	7 / 105 (6.67%)	5 / 101 (4.95%)	1 / 48 (2.08%)
occurrences (all)	7	5	1
Confusional State			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Depression			
subjects affected / exposed	7 / 105 (6.67%)	2 / 101 (1.98%)	4 / 48 (8.33%)
occurrences (all)	7	2	4

Insomnia			
subjects affected / exposed	9 / 105 (8.57%)	6 / 101 (5.94%)	2 / 48 (4.17%)
occurrences (all)	9	6	2
Sleep Disorder			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Depressed Mood			
subjects affected / exposed	0 / 105 (0.00%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Restlessness			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Hepatic Enzyme Increased			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
International Normalised Ratio Abnormal			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Weight Increased			
subjects affected / exposed	2 / 105 (1.90%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences (all)	2	2	0
Weight Decreased			
subjects affected / exposed	6 / 105 (5.71%)	1 / 101 (0.99%)	2 / 48 (4.17%)
occurrences (all)	12	1	2
Blood Cholesterol Increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Haemoglobin Decreased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Blood Creatinin Increased			

subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
C-Reactive Protein Increased			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Transaminases Increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
White Blood Cell Count Decreased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
White Blood Cell Count Increased			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Anal Injury			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Arthropod Bite			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	3	0	0
Drug Toxicity			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Procedural Pain			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Seroma			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Traumatic Haemorrhage			

subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Wrist Fracture			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Ankle Fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Thermal Burn			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Upper Lumb Fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Hand Fracture			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Injury			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Excoration			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Radiation Skin Injury			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Wound Complication			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

Palpitations			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Atrial Fibrillation			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	11 / 105 (10.48%)	7 / 101 (6.93%)	3 / 48 (6.25%)
occurrences (all)	11	7	3
Dysgeusia			
subjects affected / exposed	3 / 105 (2.86%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	4	1	1
Facial Paresis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	13 / 105 (12.38%)	11 / 101 (10.89%)	6 / 48 (12.50%)
occurrences (all)	19	14	6
Hyperaesthesia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Hypogeusia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	3 / 105 (2.86%)	2 / 101 (1.98%)	2 / 48 (4.17%)
occurrences (all)	3	2	4
Paraesthesia			
subjects affected / exposed	2 / 105 (1.90%)	3 / 101 (2.97%)	1 / 48 (2.08%)
occurrences (all)	2	4	1
Parkinsonism			

subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	3 / 105 (2.86%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	3	1	0
Syncope			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
Amnesia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Neuropathy Peripheral			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Migraine			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Memory Impairment			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Paresis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Speech Disorder			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 105 (5.71%)	7 / 101 (6.93%)	1 / 48 (2.08%)
occurrences (all)	7	8	4

Neutropenia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Leukopenia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	1	0	2
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Cataract			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Conjunctivitis			
subjects affected / exposed	6 / 105 (5.71%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	7	0	1
Dry Eye			
subjects affected / exposed	5 / 105 (4.76%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	6	2	1
Erythema of Eyelid			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Eye Inflammation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Eye Irritation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Eye Pain			

subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	3	0	2
Eye Pruritus			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	3	0	1
Eyelid Pain			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Eyelids Pruritus			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Foreign Body Sensation In Eyes			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Lacrimation Increased			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Madarosis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	3
Ocular Hyperaemia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Panophthalmitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Visual Acuity Reduced			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Blepharospasm			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Ectropion			

subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Eyelid Irritation			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Eyelid Oedema			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Glaucoma			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Photophobia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Vision Blurred			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Abdominal Pain			
subjects affected / exposed	6 / 105 (5.71%)	6 / 101 (5.94%)	3 / 48 (6.25%)
occurrences (all)	9	7	3
Abdominal Pain Upper			
subjects affected / exposed	3 / 105 (2.86%)	3 / 101 (2.97%)	2 / 48 (4.17%)
occurrences (all)	3	3	2
Abdominal Pain Lower			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Anal Fissure			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Anal Haemorrhage			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

Aphthous Stomatitis			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Cheilitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	11 / 105 (10.48%)	8 / 101 (7.92%)	3 / 48 (6.25%)
occurrences (all)	12	10	3
Diarrhoea			
subjects affected / exposed	62 / 105 (59.05%)	24 / 101 (23.76%)	28 / 48 (58.33%)
occurrences (all)	97	28	42
Diarrhoea Haemorrhagic			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Dry Mouth			
subjects affected / exposed	8 / 105 (7.62%)	5 / 101 (4.95%)	4 / 48 (8.33%)
occurrences (all)	9	5	6
Duodenal Ulcer			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Duodenitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	10 / 105 (9.52%)	6 / 101 (5.94%)	5 / 48 (10.42%)
occurrences (all)	10	7	5
Dysphagia			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	3	0	0
Enteritis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Flatulence			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0

Gastric Ulcer			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Gastroesophageal Reflux Disease			
subjects affected / exposed	1 / 105 (0.95%)	2 / 101 (1.98%)	5 / 48 (10.42%)
occurrences (all)	1	2	5
Gingival Bleeding			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Glossodynia			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
Haematochezia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Haemorrhoids			
subjects affected / exposed	4 / 105 (3.81%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	6	0	1
Mouth Haemorrhage			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Mouth Ulceration			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	3	0	0
Nausea			
subjects affected / exposed	36 / 105 (34.29%)	29 / 101 (28.71%)	12 / 48 (25.00%)
occurrences (all)	42	34	15
Proctalgia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Pruritus Ani			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

Stomatitis			
subjects affected / exposed	5 / 105 (4.76%)	1 / 101 (0.99%)	2 / 48 (4.17%)
occurrences (all)	5	1	2
Swollen Tongue			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Vomiting			
subjects affected / exposed	24 / 105 (22.86%)	12 / 101 (11.88%)	10 / 48 (20.83%)
occurrences (all)	28	17	11
Abdominal Distension			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Abdominal Rigidity			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Abdominal Tenderness			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Anal Discomfort			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Epigastric Discomfort			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Frequent Bowel Movements			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Lip Dry			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0

Oral Mucosal Blistering subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	1 / 101 (0.99%) 1	0 / 48 (0.00%) 0
Oral Mucosal Exfoliation subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	0 / 101 (0.00%) 0	1 / 48 (2.08%) 1
Tooth Disorder subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	0 / 101 (0.00%) 0	1 / 48 (2.08%) 1
Reflux Oesophagitis subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	1 / 101 (0.99%) 1	0 / 48 (0.00%) 0
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	1 / 105 (0.95%) 1	0 / 101 (0.00%) 0	0 / 48 (0.00%) 0
Hepatic Pain subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	1 / 101 (0.99%) 1	0 / 48 (0.00%) 0
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	6 / 105 (5.71%) 7	1 / 101 (0.99%) 1	7 / 48 (14.58%) 8
Acrodermatitis subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	2 / 101 (1.98%) 2	0 / 48 (0.00%) 0
Alopecia subjects affected / exposed occurrences (all)	51 / 105 (48.57%) 64	23 / 101 (22.77%) 26	25 / 48 (52.08%) 30
Blister subjects affected / exposed occurrences (all)	1 / 105 (0.95%) 1	0 / 101 (0.00%) 0	0 / 48 (0.00%) 0
Decubitus Ulcer subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	1 / 101 (0.99%) 1	0 / 48 (0.00%) 0
Dermatitis			

subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
Dermatitis Acneiform			
subjects affected / exposed	5 / 105 (4.76%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	6	0	1
Dermatitis Contact			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Drug Eruption			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Dry Skin			
subjects affected / exposed	26 / 105 (24.76%)	6 / 101 (5.94%)	8 / 48 (16.67%)
occurrences (all)	35	7	8
Ecchymosis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Eczema			
subjects affected / exposed	4 / 105 (3.81%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	4	0	0
Erythema			
subjects affected / exposed	12 / 105 (11.43%)	0 / 101 (0.00%)	3 / 48 (6.25%)
occurrences (all)	16	0	8
Hair Colour Changes			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
Hair Disorder			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Hair Growth Abnormal			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Hair Texture Abnormal			
subjects affected / exposed	4 / 105 (3.81%)	1 / 101 (0.99%)	3 / 48 (6.25%)
occurrences (all)	5	1	3
Hangnail			

subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Hypertrichosis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
Ingrowing Nail			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Intertrigo			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Itching Scar			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Nail Disorder			
subjects affected / exposed	7 / 105 (6.67%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	7	0	0
Nail Growth Abnormal			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Onychoclasia			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	3 / 48 (6.25%)
occurrences (all)	2	0	4
Onycholysis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Palmar Erythema			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Palmar-Plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

Pruritus			
subjects affected / exposed	14 / 105 (13.33%)	12 / 101 (11.88%)	4 / 48 (8.33%)
occurrences (all)	18	14	6
Pruritus Generalised			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Psoriasis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	52 / 105 (49.52%)	17 / 101 (16.83%)	14 / 48 (29.17%)
occurrences (all)	83	23	15
Rash Erythematous			
subjects affected / exposed	0 / 105 (0.00%)	2 / 101 (1.98%)	1 / 48 (2.08%)
occurrences (all)	0	2	1
Rash Generalised			
subjects affected / exposed	7 / 105 (6.67%)	0 / 101 (0.00%)	4 / 48 (8.33%)
occurrences (all)	8	0	4
Rash Macular			
subjects affected / exposed	4 / 105 (3.81%)	2 / 101 (1.98%)	1 / 48 (2.08%)
occurrences (all)	5	2	1
Rash Maculo-Papular			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	2	1	0
Rash Papular			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Rash Pruritic			
subjects affected / exposed	8 / 105 (7.62%)	2 / 101 (1.98%)	2 / 48 (4.17%)
occurrences (all)	9	2	2
Rosacea			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	1	1	2
Skin Exfoliation			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	3	0	2

Skin Fissures			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	4	0	1
Skin Irritation			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Skin Lesion			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Skin Reaction			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Skin Toxicity			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	2
Skin Ulcer			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Swelling Face			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Urticaria			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	5 / 105 (4.76%)	0 / 101 (0.00%)	3 / 48 (6.25%)
occurrences (all)	5	0	3
Haematuria			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	2	0	1
Chromaturia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			

subjects affected / exposed occurrences (all)	2 / 105 (1.90%) 2	0 / 101 (0.00%) 0	1 / 48 (2.08%) 1
Urinary Incontinence subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	1 / 101 (0.99%) 1	1 / 48 (2.08%) 1
Urinary Bladder Haemorrhage subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	0 / 101 (0.00%) 0	0 / 48 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 105 (0.00%) 0	0 / 101 (0.00%) 0	0 / 48 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	12 / 105 (11.43%) 15	11 / 101 (10.89%) 13	1 / 48 (2.08%) 1
Back Pain subjects affected / exposed occurrences (all)	11 / 105 (10.48%) 12	9 / 101 (8.91%) 11	0 / 48 (0.00%) 0
Bone Pain subjects affected / exposed occurrences (all)	7 / 105 (6.67%) 7	12 / 101 (11.88%) 12	5 / 48 (10.42%) 6
Flank Pain subjects affected / exposed occurrences (all)	1 / 105 (0.95%) 1	0 / 101 (0.00%) 0	0 / 48 (0.00%) 0
Joint Swelling subjects affected / exposed occurrences (all)	2 / 105 (1.90%) 2	2 / 101 (1.98%) 2	0 / 48 (0.00%) 0
Muscle Spasms subjects affected / exposed occurrences (all)	9 / 105 (8.57%) 12	2 / 101 (1.98%) 2	9 / 48 (18.75%) 10
Musculoskeletal Chest Pain subjects affected / exposed occurrences (all)	4 / 105 (3.81%) 5	9 / 101 (8.91%) 12	2 / 48 (4.17%) 4
Musculoskeletal Pain			

subjects affected / exposed	3 / 105 (2.86%)	4 / 101 (3.96%)	2 / 48 (4.17%)
occurrences (all)	4	5	2
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Mialgia			
subjects affected / exposed	9 / 105 (8.57%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences (all)	9	3	0
Neck Pain			
subjects affected / exposed	3 / 105 (2.86%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	3	1	0
Pain In Extremity			
subjects affected / exposed	4 / 105 (3.81%)	9 / 101 (8.91%)	0 / 48 (0.00%)
occurrences (all)	4	10	0
Pathological Fracture			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Rotator Cuff Syndrome			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Sensation Of Heaviness			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Intervertebral Disc Compression			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Joint Effusion			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Monarthrititis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Muscular Weakness			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Osteoarthritis			

subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Osteoporosis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Synovial Cyst			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Breast Cellulitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	2 / 105 (1.90%)	4 / 101 (3.96%)	3 / 48 (6.25%)
occurrences (all)	3	4	4
Cellulitis			
subjects affected / exposed	3 / 105 (2.86%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	3	2	0
Cystitis			
subjects affected / exposed	6 / 105 (5.71%)	1 / 101 (0.99%)	2 / 48 (4.17%)
occurrences (all)	6	1	4
Dermatitis Infected			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Ear Infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Enterovirus Infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Erysipelas			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1

Fungal Rash			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Fungal Skin Infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Gastrointestinal Infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Herpes Simplex			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 105 (1.90%)	3 / 101 (2.97%)	2 / 48 (4.17%)
occurrences (all)	3	3	4
Laryngitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Localised Infection			
subjects affected / exposed	2 / 105 (1.90%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	2	1	0
Lower Respiratory Tract Infection			
subjects affected / exposed	4 / 105 (3.81%)	4 / 101 (3.96%)	0 / 48 (0.00%)
occurrences (all)	4	4	0
Nail Infection			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	4	0	0
Nasopharyngitis			
subjects affected / exposed	4 / 105 (3.81%)	4 / 101 (3.96%)	1 / 48 (2.08%)
occurrences (all)	8	5	1
Oesophageal Candidiasis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0

Oral Candidiasis			
subjects affected / exposed	2 / 105 (1.90%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	2	1	0
Oral Herpes			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Rash Pustular			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	5	0	0
Respiratory Tract Infection			
subjects affected / exposed	2 / 105 (1.90%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	2	1	0
Rhinitis			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	3	0	1
Sinusitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Skin Infection			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Tonsillitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 105 (0.95%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences (all)	2	2	0
Urinary Tract Infection			
subjects affected / exposed	6 / 105 (5.71%)	5 / 101 (4.95%)	5 / 48 (10.42%)
occurrences (all)	7	6	6
Vaginal Candidiasis			
subjects affected / exposed	3 / 105 (2.86%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	3	1	1
Vaginal Infection			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	3	0	1

Wound Infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Paronychia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Folliculitis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Fungal Infection			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	1 / 48 (2.08%)
occurrences (all)	0	1	1
Gastroenteritis Viral			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Herpes Zoster			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	2 / 48 (4.17%)
occurrences (all)	0	0	2
Lymphangitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	3 / 48 (6.25%)
occurrences (all)	0	0	4
Pneumonia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	2 / 48 (4.17%)
occurrences (all)	0	1	2
Tooth Abscess			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Tooth Infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Vulvovaginal Mycotic Infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	0	0	1
Candidiasis			
subjects affected / exposed	0 / 105 (0.00%)	2 / 101 (1.98%)	0 / 48 (0.00%)
occurrences (all)	0	2	0

Impetigo			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Breast Infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Eye Infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	9 / 105 (8.57%)	3 / 101 (2.97%)	3 / 48 (6.25%)
occurrences (all)	11	3	5
Decreased Appetite			
subjects affected / exposed	8 / 105 (7.62%)	6 / 101 (5.94%)	1 / 48 (2.08%)
occurrences (all)	8	6	1
Dehydration			
subjects affected / exposed	3 / 105 (2.86%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	3	0	1
Diabetes Mellitus			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	1	1	0
Fluid Retention			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Gout			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	1 / 48 (2.08%)
occurrences (all)	1	0	1
Hypercalcaemia			

subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 105 (0.95%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	4	1	0
Hypocalcaemia			
subjects affected / exposed	2 / 105 (1.90%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	4 / 105 (3.81%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	5	1	0
Hypophosphataemia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	1	0	0
Increased Appetite			
subjects affected / exposed	0 / 105 (0.00%)	1 / 101 (0.99%)	0 / 48 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 101 (0.00%)	0 / 48 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Stratum 2: Tamoxifen + Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 35 (80.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumor Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Uterine Leiomyoma			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Haematoma			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hot Flush			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	6		
Hypertension			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Lymphoedema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Orthostatic Hypotension			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pallor			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Phlebitis Superficial			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Varicose Vein			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Venous Insufficiency			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Surgical and medical procedures			
Preventive Surgery			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	5 / 35 (14.29%)		
occurrences (all)	6		
Chest Discomfort			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Fatigue			
subjects affected / exposed	6 / 35 (17.14%)		
occurrences (all)	9		
General Physical Health Deterioration			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Influenza Like Illness			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Mucosal Dryness			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Mucosal Imflammation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Oedema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Oedema Peripheral			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	3		
Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Pirexia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Adverse Drug Reaction			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Chest Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Face Oedema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Local Swelling			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Mucosal Haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Non-Cardiac Chest Pain			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Seasonal Allergy			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Allergy To Plants			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Breast Inflammation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Breast Pain			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Cystocele			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dyspareunia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Genital Rash			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pelvic Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vaginal Discharge			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Vulval Erythema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vulvovaginal Pruritus			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Genital Discharge			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Vaginal Haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Uterine Polyp			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Metrorrhagia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vulvovaginal Dryness			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dysmenorrhoea			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pruritus Genital			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Chronic Obstructive Pulmonary Disease			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		
Dispnoea			
subjects affected / exposed	6 / 35 (17.14%)		
occurrences (all)	6		
Dispnoea Exertional			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Lung Infiltration			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nasal Congestion			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nasal Dryness			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nasal Imflammation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nasal Mucosal Disorder			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pharyngolaryngeal Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pleural Effusion			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Productive Cough			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pulmonary Congestion			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rhinitis Allergic			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Confusional State			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Insomnia			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Sleep Disorder			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Depressed Mood			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Restlessness			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hepatic Enzyme Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
International Normalised Ratio Abnormal			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Weight Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Weight Decreased			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Blood Cholesterol Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Haemoglobin Decreased			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Blood Creatinin Increased			

subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
C-Reactive Protein Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Transaminases Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
White Blood Cell Count Decreased			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
White Blood Cell Count Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Anal Injury			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Arthropod Bite			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Drug Toxicity			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Procedural Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Seroma			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Traumatic Haemorrhage			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Wrist Fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Ankle Fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Thermal Burn			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Upper Lumb Fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hand Fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Injury			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Excoriation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Radiation Skin Injury			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Wound Complication			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Cardiac disorders			
Angina Pectoris			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Palpitations			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Atrial Fibrillation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	2		
Dysgeusia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Facial Paresis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	3		
Hyperaesthesia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hypogeusia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Parkinsonism			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Neuropathy Peripheral			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Neuralgia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Memory Impairment			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Paresis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Speech Disorder			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		

Neutropenia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Cataract			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dry Eye			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Erythema of Eyelid			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eye Inflammation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eye Irritation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eye Pain			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eye Pruritus			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Eyelid Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eyelids Pruritus			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Foreign Body Sensation In Eyes			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Lacrimation Increased			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Madarosis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Ocular Hyperaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Panophthalmitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Visual Acuity Reduced			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Blepharospasm			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Diplopia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Ectropion			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eyelid Irritation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Eyelid Oedema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Glaucoma			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Photophobia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vision Blurred			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Discomfort			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Abdominal Pain			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Abdominal Pain Upper			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Abdominal Pain Lower			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Anal Fissure			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Anal Haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Aphthous Stomatitis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Cheilitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Constipation			
subjects affected / exposed	5 / 35 (14.29%)		
occurrences (all)	5		
Diarrhoea			
subjects affected / exposed	7 / 35 (20.00%)		
occurrences (all)	10		
Diarrhoea Haemorrhagic			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dry Mouth			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Duodenal Ulcer			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Duodenitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Dysphagia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Enteritis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		

Gastric Ulcer			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Gingival Bleeding			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Glossodynia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Haematochezia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Mouth Haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Mouth Ulceration			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	6 / 35 (17.14%)		
occurrences (all)	7		
Proctalgia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pruritus Ani			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Stomatitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Swollen Tongue			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	4		
Abdominal Distension			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Abdominal Rigidity			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Abdominal Tenderness			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Anal Discomfort			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Epigastric Discomfort			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Frequent Bowel Movements			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Lip Dry			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Oesophagitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Oral Mucosal Blistering subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Oral Mucosal Exfoliation subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Tooth Disorder subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Reflux Oesophagitis subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Hepatobiliary disorders Hyperbilirubinaemia subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Hepatic Pain subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Skin and subcutaneous tissue disorders Acne subjects affected / exposed occurrences (all)	1 / 35 (2.86%) 1		
Acrodermatitis subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Alopecia subjects affected / exposed occurrences (all)	5 / 35 (14.29%) 5		
Blister subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Decubitus Ulcer subjects affected / exposed occurrences (all)	0 / 35 (0.00%) 0		
Dermatitis			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dermatitis Acneiform			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dermatitis Contact			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Drug Eruption			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dry Skin			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Ecchymosis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hair Colour Changes			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hair Disorder			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hair Growth Abnormal			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hair Texture Abnormal			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Hangnail			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Hypertrichosis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Ingrowing Nail			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Intertrigo			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Itching Scar			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Nail Disorder			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nail Growth Abnormal			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Onychoclasia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Onycholysis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Palmar Erythema			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Palmar-Plantar Erythrodysesthesia Syndrome			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Pruritus			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Pruritus Generalised			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Psoriasis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Rash Erythematous			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rash Generalised			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rash Macular			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rash Maculo-Papular			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rash Papular			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rash Pruritic			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rosacea			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Skin Exfoliation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Skin Fissures			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Skin Irritation			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Skin Lesion			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Skin Reaction			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Skin Toxicity			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Skin Ulcer			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Swelling Face			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Chromaturia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pollakiuria			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Urinary Incontinence			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Urinary Bladder Haemorrhage			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	3		
Back Pain			
subjects affected / exposed	3 / 35 (8.57%)		
occurrences (all)	4		
Bone Pain			
subjects affected / exposed	4 / 35 (11.43%)		
occurrences (all)	4		
Flank Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Joint Swelling			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Muscle Spasms			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	4		
Musculoskeletal Chest Pain			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Musculoskeletal Pain			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Mialgia			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Neck Pain			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pain In Extremity			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pathological Fracture			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rotator Cuff Syndrome			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Sensation Of Heaviness			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Intervertebral Disc Compression			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Joint Effusion			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Monarthritis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Muscular Weakness			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Osteoarthritis			

subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Osteoporosis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Synovial Cyst			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Breast Cellulitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Cellulitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Dermatitis Infected			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Ear Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Enterovirus Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Erysipelas			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	6		

Fungal Rash			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Fungal Skin Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Gastrointestinal Infection			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Herpes Simplex			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Laryngitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Localised Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Lower Respiratory Tract Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nail Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Nasopharyngitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Oesophageal Candidiasis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Oral Candidiasis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Oral Herpes			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Rash Pustular			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Respiratory Tract Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Rhinitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Skin Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Urinary Tract Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vaginal Candidiasis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vaginal Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Wound Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Paronychia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Folliculitis			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Fungal Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Gastroenteritis Viral			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Herpes Zoster			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Lymphangitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Tooth Abscess			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Tooth Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Vulvovaginal Mycotic Infection			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Candidasis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		

Impetigo			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Respiratory Tract Infection Viral			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Breast Infection			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Eye Infection			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Anorexia			
subjects affected / exposed	2 / 35 (5.71%)		
occurrences (all)	2		
Decreased Appetite			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Dehydration			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Diabetes Mellitus			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Fluid Retention			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hypercalcaemia			

subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hypoalbuminaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hypocalcaemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		
Hypophosphataemia			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Increased Appetite			
subjects affected / exposed	0 / 35 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	1 / 35 (2.86%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported