Study Of "Continuous Use" Of Celecoxib Vs. "Usual or Intermittent Use"

This study has been completed.

Sponsor:
Pfizer

Information provided by:
Pfizer

ClinicalTrials.gov Identifier:
NCT00139776

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History of Changes

Results First Received: February 20, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Osteoarthritis, Knee Osteoarthritis, Hip
Intervention:	Drug: Celecoxib

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
111 centers in the Americas and Europe enrolled and treated subjects (2 centers in Belgium, 4 centers in Brazil, 20 centers in Canada, 5 centers in Chile, 5 centers in Columbia, 1 center in France, 15 centers in the United Kingdom, and 59 centers in the United States).

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
17 participants completed Open-label run-in Period II and were randomized to Period III Double Blind but not treated.

Reporting Groups

	Description
Wash-Out: Discontinue Non-Steroidal Anti-Inflammatories	Period I (14+/-2 days) wash out and discontinuation of non-steroidal anti-inflammatories (NSAIDs) leading to osteoarthritis (OA) flare.
Open-Label Celecoxib Run-in Period	Period II (14+/-2 days) run-in treatment with open label celecoxib to observe successful treatment of flare. Participants successfully treated randomized to 2 treatment groups in Period III (overall study).
Celecoxib 200mg Continuous Use	Period III Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	

	Period III Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Participant Flow for 3 periods

Period 1: Period I

	Wash-Out: Discontinue Non-Steroidal Anti-Inflammatories	Open-Label Celecoxib Run-in Period	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
STARTED	1772	0	0	0
COMPLETED	1197	0	0	0
NOT COMPLETED	575	0	0	0
Did not enter Period II	575	0	0	0

Period 2: Period II

	Wash-Out: Discontinue Non-Steroidal Anti-Inflammatories	Open-Label Celecoxib Run-in Period	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
STARTED	0	1197	0	0
COMPLETED	0	875	0	0
NOT COMPLETED	0	322	0	0
Not Randomized into Period III	0	322	0	0

Period 3: Period III

	Wash-Out: Discontinue Non-Steroidal Anti-Inflammatories	Open-Label Celecoxib Run-in Period	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
STARTED	0	0	431 [1]	427 [2]
COMPLETED	0	0	355	321
NOT COMPLETED	0	0	76	106
Adverse Event	0	0	22	23
Unknown	0	0	23	34
Lack of Efficacy	0	0	10	24
Lost to Follow-up	0	0	5	4
Withdrawal by Subject	0	0	16	21

[1] Randomized 440: 9 participants not treated
[2] Randomized 435: 8 participants not treated

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.
Total	Total of all reporting groups

Baseline Measures

	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use	Total
Number of Participants [units: participants]	**431**	**427**	**858**
Age [units: years] Mean ± Standard Deviation	**58.5 ± 10.00**	**58.7 ± 9.6**	**58.6 ± 9.8**
Gender [units: participants]			
Female	**317**	**303**	**620**
Male	**114**	**124**	**238**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Flare Events Per Time of Exposure to Study Medication [Time Frame: Period III (22 weeks)]

Measure Type	Primary
Measure Title	Number of Flare Events Per Time of Exposure to Study Medication
Measure Description	Number of flare events per month during Period III (calculated as number of flares divided by number of months participant was enrolled during Period III). Flare was determined using pre-defined criteria, using an interactive voice response system.
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
Number of Participants Analyzed [units: participants]	**431**	**427**
Number of Flare Events Per Time of Exposure to Study Medication	**0.54 ± 0.74**	**0.93 ± 1.01**

[units: flare events per month] Mean ± Standard Deviation		

Statistical Analysis 1 for Number of Flare Events Per Time of Exposure to Study Medication

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Null hypothesis for primary outcome is that there is no difference in the number of flares observed between the 2 treatment arms of celecoxib 200mg continuous use and celecoxib 200mg intermittent use. Sample size calculation: Sufficient number of participants were randomized to provide at least 80% power to detect an estimated effect size of 0.2 using a 2-sided t-test at a 0.05 significant level.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

2. Secondary: Time to Occurrence of First Osteoarthritis (OA) Flare [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Time to Occurrence of First Osteoarthritis (OA) Flare
Measure Description	Time from first dose of double blind medication (start of Period III) to occurrence of first OA flare. Flare was determined using pre-defined criteria, using an interactive voice response system
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Time to Occurrence of First Osteoarthritis (OA) Flare [units: days] Median (95% Confidence Interval)	**16.0 (14.0 to 22.0)**	**8.0 (8.0 to 9.0)**

Statistical Analysis 1 for Time to Occurrence of First Osteoarthritis (OA) Flare

Groups [1]	All groups
Method [2]	Log Rank
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Kaplan-Meier analysis
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

3. Secondary: Proportion of Days Free From Osteoarthritis (OA) Flare [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Proportion of Days Free From Osteoarthritis (OA) Flare
Measure Description	Number of days subject was free from OA flare divided by number of days on study medication in Period III. Flare was determined using pre-defined criteria, using an interactive voice response system.
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Proportion of Days Free From Osteoarthritis (OA) Flare [units: proportion of days free from OA flare] Mean ± Standard Deviation	**0.77 ± 0.28**	**0.67 ± 0.30**

Statistical Analysis 1 for Proportion of Days Free From Osteoarthritis (OA) Flare

Groups [1]	All groups
	ANOVA

Method [2]	
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

4. Secondary: Proportion of Days in Osteoarthritis (OA) Flare [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Proportion of Days in Osteoarthritis (OA) Flare
Measure Description	Number of days subject was in OA flare divided by number of days on study medication in Period III. Subjects may have more than one flare. Flare was determined using pre-defined criteria, using an interactive voice response system.
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Proportion of Days in Osteoarthritis (OA) Flare [units: proportion of days in OA flare] Mean ± Standard Deviation	**0.23 ± 0.28**	**0.33 ± 0.30**

Statistical Analysis 1 for Proportion of Days in Osteoarthritis (OA) Flare

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

5. Secondary: Arthritis Pain Numerical Rating Scale (NRS) [Time Frame: Period III]

Measure Type	Secondary
Measure Title	Arthritis Pain Numerical Rating Scale (NRS)
Measure Description	Participant rated intensity of osteoarthritis pain on categorical scale from 0 (no pain) to 10 (worst pain). Scores analyzed as area under the curve (AUC) of participant's scores from each assessment in Period III.
Time Frame	Period III
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication. These data are presented by the weeks from the start of Period II, 2 weeks before randomization. The weeks post-randomization, Period III, are different from the study weeks i.e. includes 2 weeks from Period II.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
Number of Participants Analyzed [units: participants]	**431**	**427**
Arthritis Pain Numerical Rating Scale (NRS) [units: scores on a scale * weeks] Least Squares Mean ± Standard Error		
Week 4 (n=415 cont; n=414 inter)	**81.7 ± 1.1**	**90.5 ± 1.1**
Week 8 (n=401 cont; n=395 inter)	**148.8 ± 2.6**	**167.0 ± 2.6**
Week 12 (n=383 cont; n=363 inter)	**212.6 ± 4.1**	**234.3 ± 4.1**
Week 16 (n=373 cont; n=339 inter)	**272.7 ± 5.9**	**297.6 ± 5.9**
Week 20 (n=362; n=323 inter)	**335.9 ± 7.8**	**361.1 ± 7.8**
Week 24 (n=350 cont; n=403 inter)	**378.1 ± 9.1**	**403.9 ± 9.2**

Statistical Analysis 1 for Arthritis Pain Numerical Rating Scale (NRS)

Groups [1]	All groups
Method [2]	ANCOVA

P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 4
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 2 for Arthritis Pain Numerical Rating Scale (NRS)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 8
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 3 for Arthritis Pain Numerical Rating Scale (NRS)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 12
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 4 for Arthritis Pain Numerical Rating Scale (NRS)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.003

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 16
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 5 for Arthritis Pain Numerical Rating Scale (NRS)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.022

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 20
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 6 for Arthritis Pain Numerical Rating Scale (NRS)

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.047

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 24
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

6. Secondary: Patient's Global Assessment of Arthritis [Time Frame: Period III]

Measure Type	Secondary
Measure Title	Patient's Global Assessment of Arthritis
Measure Description	Participant's response to question "Considering all the ways the osteoarthritis in your hip or knee affects you, how are you doing today?" on scale from 1 (very good) to 5 (very poor). Scores analyzed as area under the curve (AUC) of participant's scores from each assessment in Period III.
Time Frame	Period III
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication.

These data are presented by the weeks from the start of Period II, 2 weeks before randomization. The weeks post-randomization, Period III, are different from the study weeks i.e. includes 2 weeks from Period II.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
Number of Participants Analyzed [units: participants]	**431**	**427**
Patient's Global Assessment of Arthritis [units: scores on a scale * weeks] Least Squares Mean ± Standard Error		
Week 4 (n=415 cont; n=414 inter)	**67.9 ± 0.68**	**71.7 ± 0.69**
Week 8 (n=401 cont; n=395 inter)	**126.0 ± 1.55**	**133.2 ± 1.56**
Week 12 (n=383 cont; n=363 inter)	**182.8 ± 2.48**	**188.7 ± 2.48**
Week 16 (n=373 cont; n=339 inter)	**236.3 ± 3.59**	**241.2 ± 3.59**
Week 20 (n=362 cont; n=323 inter)	**292.4 ± 4.83**	**293.8 ± 4.84**
Week 24 (n=350 cont; n=309 inter)	**329.2 ± 5.75**	**328.9 ± 5.76**

Statistical Analysis 1 for Patient's Global Assessment of Arthritis

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 4
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 2 for Patient's Global Assessment of Arthritis

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 8
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 3 for Patient's Global Assessment of Arthritis

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.096

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 12
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 4 for Patient's Global Assessment of Arthritis

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.338

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 16
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 5 for Patient's Global Assessment of Arthritis

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.832

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 20
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 6 for Patient's Global Assessment of Arthritis

Groups [1]	All groups

Method [2]	ANCOVA
P Value [3]	0.972

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Week 24
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

7. Secondary: Physician's Global Assessment of Arthritis at Final Visit [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Physician's Global Assessment of Arthritis at Final Visit
Measure Description	Physician assessed each participant's disease symptoms on a categorical scale from 1 (very good) to 5 (very poor).
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Physician's Global Assessment of Arthritis at Final Visit [units: participants]		
Grade 1 (very good)	**68**	**39**
Grade 2 (good)	**242**	**244**
Grade 3 (fair)	**91**	**113**
Grade 4 (poor)	**23**	**27**
Grade 5 (very poor)	**2**	**2**

Statistical Analysis 1 for Physician's Global Assessment of Arthritis at Final Visit

Groups [1]	All groups

Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.0046

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Test of row mean score differences based on modified ridits (standardizing the mid-rank)
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Overall p-value Threshold for statistical significance p<0.05

8. Secondary: Total Rescue Medication Taken (Mean) [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Total Rescue Medication Taken (Mean)
Measure Description	Total amount of rescue medication (acetaminophen in milligrams [mg]) taken per month per participant
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication. Subjects who did not take rescue medication were assumed to have taken 0mg and were included in the analysis. Number of subjects taking rescue medication: continuous use n=220; intermittent use n=239.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Total Rescue Medication Taken (Mean) [units: mg taken per month per participant] Mean ± Standard Deviation	**1566 ± 4840**	**2428 ± 4974**

Statistical Analysis 1 for Total Rescue Medication Taken (Mean)

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.0102

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

9. Secondary: Proportion of Days on Rescue Medication [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Proportion of Days on Rescue Medication
Measure Description	Days on rescue medication divided by number of days on study medication in Period III
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication. Number of subjects taking rescue medication: continuous use n=220; intermittent use n=239. Subjects who did not take rescue medication were calculated as 0 and included in the analysis.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
Number of Participants Analyzed [units: participants]	**431**	**427**
Proportion of Days on Rescue Medication [units: proportion of days] Mean ± Standard Deviation	**0.044 ± 0.102**	**0.069 ± 0.121**

Statistical Analysis 1 for Proportion of Days on Rescue Medication

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	0.0012

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Treatment as fixed effect
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

10. Secondary: Days on Flare Medication [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Days on Flare Medication
Measure Description	Number of days on flare medication per month per subject calculated as number of days on flare medication divided by the number of days on study medication in Period III
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication. Subjects who did not take flare medication were calculated as 0 and included in the analysis. Number of subjects taking flare medication: continuous use n=282; intermittent use n=339.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Days on Flare Medication [units: days on medication per month per subject] Mean ± Standard Deviation	**6.589 ± 8.589**	**9.793 ± 9.253**

Statistical Analysis 1 for Days on Flare Medication

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:

	Threshold for statistical significance p<0.05

11. Secondary: Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores
Measure Description	Score at end of Period III minus score at start of Period III. WOMAC assesses subject responses to 24 components regarding subscales of pain, stiffness and physical function (score range: 0=none to 4= extreme). Total score is sum of the 3 subscale scores. Negative change indicates improvement.
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication. Number of subjects evaluable: continuous use Period III start n=428, end n=427; intermittent use Period III start n=424, end n=424

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores [units: scores on a scale] Least Squares Mean ± Standard Error		
Total WOMAC score	**1.60 ± 0.71**	**4.99 ± 0.71**
WOMAC pain subscale	**0.37 ± 0.15**	**1.18 ± 0.15**
WOMAC stiffness subscale	**0.12 ± 0.07**	**0.40 ± 0.07**
WOMAC physical function subscale	**1.13 ± 0.51**	**3.43 ± 0.51**

Statistical Analysis 1 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Total WOMAC score
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 2 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Continuous Use
Mean Difference (Final Values) [2]	1.60
Standard Error of the mean	± 0.71
95% Confidence Interval	(0.21 to 2.99)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Total WOMAC score - Continuous use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

Statistical Analysis 3 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Intermittent Use
Mean Difference (Final Values) [2]	4.99
Standard Error of the mean	± 0.71
95% Confidence Interval	(3.60 to 6.38)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Total WOMAC score - Intermittent use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

Statistical Analysis 4 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC pain subscale
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 5 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Continuous Use
Mean Difference (Final Values) [2]	0.37
Standard Error of the mean	± 0.15

95% Confidence Interval	(0.06 to 0.67)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC pain subscale - Continuous use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

Statistical Analysis 6 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Intermittent Use
Mean Difference (Final Values) [2]	1.18
Standard Error of the mean	± 0.15
95% Confidence Interval	(0.88 to 1.49)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC pain subscale - Intermittent use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

Statistical Analysis 7 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.004

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC stiffness subscale
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance $p<0.05$

Statistical Analysis 8 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Continuous Use
Mean Difference (Final Values) [2]	0.12
Standard Error of the mean	± 0.07
95% Confidence Interval	(-0.02 to 0.25)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC stiffness subscale - Continuous use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

Statistical Analysis 9 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Intermittent Use

Mean Difference (Final Values) [2]	0.40
Standard Error of the mean	± 0.07
95% Confidence Interval	(0.26 to 0.53)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC stiffness subscale - Intermittent use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

Statistical Analysis 10 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.002

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC physical function subscale
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 11 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Continuous Use
Mean Difference (Final Values) [2]	1.13
Standard Error of the mean	± 0.51
95% Confidence Interval	(0.13 to 2.14)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC physical function subscale - Continuous use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

Statistical Analysis 12 for Change in Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	Celecoxib 200mg Intermittent Use
Mean Difference (Final Values) [2]	3.43
Standard Error of the mean	± 0.51
95% Confidence Interval	(2.42 to 4.43)

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC physical function subscale - Intermittent use
[2]	Other relevant estimation information:
	Change in LSmean (score at end of Period III minus score at start of Period III)

12. Secondary: Area Under the Curve (AUCs) of Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores [Time Frame: Period III (22 weeks)]

Measure Type	Secondary
Measure Title	Area Under the Curve (AUCs) of Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores
Measure Description	WOMAC assesses subject responses to 24 components regarding subscales of pain, stiffness and physical function (score range: 0=none to 4= extreme). Total score is sum of the 3 subscale scores. Scores analyzed as area under the curve (AUC) of participant's WOMAC scores from each assessment in Period III.
Time Frame	Period III (22 weeks)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication.
Number of subjects evaluable: continuous use Period III start n=428, end n=427; intermittent use Period III start n=424, end n=424

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Area Under the Curve (AUCs) of Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores [units: scores on a scale * weeks] Mean ± Standard Deviation		
Total WOMAC score	**604.9 ± 313.10**	**693.6 ± 317.30**
WOMAC pain subscale	**119.2 ± 63.36**	**138.4 ± 65.95**
WOMAC stiffness subscale	**54.5 ± 27.57**	**62.1 ± 27.7**
WOMAC physical function subscale	**431.4 ± 229.38**	**493.6 ± 230.74**

Statistical Analysis 1 for Area Under the Curve (AUCs) of Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC total score
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate

[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 2 for Area Under the Curve (AUCs) of Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC pain subscale
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 3 for Area Under the Curve (AUCs) of Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC stiffness subscale
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 4 for Area Under the Curve (AUCs) of Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Scores

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	WOMAC physical function subscale
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

13. Other Pre-specified: Change in Medical Outcomes Study Sleep Scale - All Assessments [Time Frame: Period III]

Measure Type	Other Pre-specified
Measure Title	Change in Medical Outcomes Study Sleep Scale - All Assessments
Measure Description	Subject assessment on 7 sleep associated categories. Raw scores are transformed to a 0-100 scale. Higher score indicates more of the outcome (e.g. more snoring, more adequate sleep). Score at end of Period III minus score at start of Period III.
Time Frame	Period III
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication. Subjects assessed per scale n=continuous use (cont); n=intermittent use (inter)

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Change in Medical Outcomes Study Sleep Scale - All Assessments [units: scores on a scale] Mean ± Standard Deviation		
Sleep disturbance (n=415 cont; n=410 inter)	**0.5 ± 15.95**	**-1.4 ± 15.55**
Snoring (n=415 cont; n=412 inter)	**0.9 ± 22.36**	**0.7 ± 21.73**
Awaken short of breath (n=417 cont; n=411 inter)	**1.9 ± 16.14**	**1.1 ± 20.00**
Quantity of sleep (n=417 cont; n=413 inter)	**-0.1 ± 0.91**	**-0.1 ± 0.89**
Sleep adequacy (n=416 cont; n=413 inter)	**0.1 ± 24.47**	**-1.3 ± 22.26**
Somnolence (n=416 cont; n=413 inter)	**1.4 ± 14.55**	**0.6 ± 13.70**
Sleep problems index I (n=416 cont; n=410 inter)	**0.9 ± 13.20**	**0.5 ± 13.18**
Sleep problems index II (n=413 cont; n=408 inter)	**0.7 ± 12.29**	**-0.1 ± 12.14**

Statistical Analysis 1 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.2712

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Sleep disturbance
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 2 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.8737

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Snoring
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 3 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.7703

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Awaken short of breath
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 4 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.3769

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Quantity of sleep
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 5 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.4075

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Sleep adequacy
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 6 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.5854

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Somnolence
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 7 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.8358

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Sleep problems index I
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 8 for Change in Medical Outcomes Study Sleep Scale - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.5878

[1]	Additional details about the analysis, such as null hypothesis and power calculation:

	Sleep problems index II
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

14. Other Pre-specified: Medical Outcomes Study Sleep Scale - Number of Participants With Optimal, Mixed and Not Optimal Sleep [Time Frame: Period III]

Measure Type	Other Pre-specified
Measure Title	Medical Outcomes Study Sleep Scale - Number of Participants With Optimal, Mixed and Not Optimal Sleep
Measure Description	Transformed score scale: 1=optimal; 0=not optimal; mixed = both optimal and non-optimal sleep during Period III
Time Frame	Period III
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Medical Outcomes Study Sleep Scale - Number of Participants With Optimal, Mixed and Not Optimal Sleep [units: participants]		
Optimal (all scores are 1)	**139**	**123**
Mixed (scores are both 1 and 0)	**166**	**165**
Not optimal (all scores are 0)	**115**	**132**

Statistical Analysis 1 for Medical Outcomes Study Sleep Scale - Number of Participants With Optimal, Mixed and Not Optimal Sleep

Groups [1]	All groups
Method [2]	Cochran-Mantel-Haenszel
P Value [3]	0.1437

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis across all 3 sleep scores for Period III

[2]	Other relevant method information, such as adjustments or degrees of freedom:
	by general association
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

15. Other Pre-specified: Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments [Time Frame: Period III]

Measure Type	Other Pre-specified
Measure Title	Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments
Measure Description	SF-12v2 is a 12 item health survey covering 7 topics. Raw scores are transformed to a 0 to 100 scale. Higher scores indicate better state of health. Score at end of Period III minus score at start of Period III.
Time Frame	Period III
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population included subjects who were randomized and received at least one dose of double blind study medication. Subjects assessed per scale n=continuous use (cont); n=intermittent use (inter)

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Measured Values

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Number of Participants Analyzed [units: participants]	**431**	**427**
Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments [units: scores on a scale] Mean ± Standard Deviation		
Physical function (n=417 cont; n=413 inter)	**1.8 ± 23.03**	**-3.2 ± 22.77**
Role physical (n=416 cont; n=412 inter)	**3.5 ± 19.93**	**-1.1 ± 20.07**
Bodily pain (n=417 cont; n=414 inter)	**3.8 ± 20.11**	**-0.3 ± 21.56**
General health (n=417 cont; n=414 inter)	**-0.3 ± 17.60**	**-0.8 ± 17.27**
Vitality (n=416 cont; n=414 inter)	**0.3 ± 20.43**	**-3.5 ± 18.34**
Social functioning (n=416 cont; n=414 inter)	**-1.9 ± 20.16**	**-3.5 ± 22.37**
Role emotional (n=417 cont; n=413 inter)	**-0.7 ± 18.62**	**-2.1 ± 19.80**
Mental health (n=416 cont; n=413 inter)	**-0.9 ± 15.57**	**-1.3 ± 16.05**
Physical component summary(n=416 cont;n=411 inter)	**9.0 ± 55.55**	**-5.2 ± 57.48**
Mental component summary (n=416 cont;n=411 inter)	**-3.1 ± 51.59**	**-10.5 ± 55.66**

Statistical Analysis 1 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Physical function
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 2 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Role physical
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 3 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Bodily pain
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 4 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA

P Value [3]	0.3097

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	General health
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 5 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.0139

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Vitality
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 6 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.1303

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Social functioning
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 7 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.1404

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Role emotional
[2]	Other relevant method information, such as adjustments or degrees of freedom:

	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 8 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.4015

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Mental health
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 9 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	<0.0001

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Physical component summary
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

Statistical Analysis 10 for Change in the Quality of Life Short Form-12v2 (SF-12v2) Scale Scores - All Assessments

Groups [1]	All groups
Method [2]	ANCOVA
P Value [3]	0.0301

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Mental component summary
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	Treatment as fixed effect and baseline as covariate
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Threshold for statistical significance p<0.05

16. Other Pre-specified: Serious Adverse Events in Open Label run-in Period [Time Frame: 2 weeks prior to double blind dosing]

Measure Type	Other Pre-specified
Measure Title	Serious Adverse Events in Open Label run-in Period
Measure Description	Serious adverse events occuring during the 2 week run-in period (Period II) when all participants were dosed with celecoxib 200 mg daily
Time Frame	2 weeks prior to double blind dosing
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
1197 participants entered the open-label run-in (period II) to allow observation of successful treatment of an osteoarthritis flare. 875 participants were randomized to double blind treatment (period III). 322 participants were not randomized.

Reporting Groups

	Description
Celecoxib 200mg Open Label	Period II run-in (2 weeks). Celecoxib 200 mg daily until resolution of screening osteoarthritis flare as defined by IVRS

Measured Values

	Celecoxib 200mg Open Label
Number of Participants Analyzed [units: participants]	**1197**
Serious Adverse Events in Open Label run-in Period [units: participants]	
Anaemia	**1**
Vitreous haemorrhage	**1**

No statistical analysis provided for Serious Adverse Events in Open Label run-in Period

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Serious Adverse Events

	Celecoxib 200mg Continuous Use	**Celecoxib 200mg Intermittent Use**
Total, serious adverse events		

# participants affected	6	10
Cardiac disorders		
Atrial fibrillation [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Coronary artery disease [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Gastrointestinal disorders		
Abdominal pain [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Gastritis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Melaena [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Pancreatitis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Rectal haemorrhage [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
General disorders		
Chest pain [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Non-cardiac chest pain [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Injury, poisoning and procedural complications		
Skin laceration [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Musculoskeletal and connective tissue disorders		
Osteoarthritis [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Metastases to central nervous system [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Squamous cell carcinoma [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Nervous system disorders		
Transient ischaemic attack [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Psychiatric disorders		
Bipolar I disorder [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Renal and urinary disorders		
Nephrolithiasis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Respiratory, thoracic and mediastinal disorders		

Acute respiratory failure † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Pulmonary oedema † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Surgical and medical procedures		
Knee arthroplasty † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Vascular disorders		
Hypertensive crisis † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (v11.1)

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
Celecoxib 200mg Continuous Use	Double blind single dose of celecoxib 200 mg daily. Placebo used as flare medication when directed.
Celecoxib 200mg Intermittent Use	Double blind placebo was taken once daily. Usual or intermittent use of celecoxib 200 mg daily as flare medication when directed.

Other Adverse Events

	Celecoxib 200mg Continuous Use	Celecoxib 200mg Intermittent Use
Total, other (not including serious) adverse events		
# participants affected	242	246
Blood and lymphatic system disorders		
Anaemia † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Lymphadenopathy † 1		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Cardiac disorders		
Angina pectoris † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Bundle branch block left † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Extrasystoles † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)

Hypertensive heart disease [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Sinus tachycardia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Tachycardia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Ear and labyrinth disorders		
Cerumen impaction [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Deafness [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Ear disorder [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Ear pain [†1]		
# participants affected / at risk	2/431 (0.46%)	2/427 (0.47%)
Eustachian tube dysfunction [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Tympanic membrane disorder [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Vertigo [†1]		
# participants affected / at risk	5/431 (1.16%)	3/427 (0.70%)
Endocrine disorders		
Goitre [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Hypothyroidism [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Eye disorders		
Cataract [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Conjunctivitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Conjunctivitis allergic [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Diplopia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Dry eye [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Eye allergy [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Eye irritation [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Glaucoma [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Lacrimation increased [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)

Myodesopsia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Vision blurred [†1]		
# participants affected / at risk	2/431 (0.46%)	1/427 (0.23%)
Visual acuity reduced [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Gastrointestinal disorders		
Abdominal discomfort [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Abdominal distension [†1]		
# participants affected / at risk	3/431 (0.70%)	1/427 (0.23%)
Abdominal hernia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Abdominal pain [†1]		
# participants affected / at risk	10/431 (2.32%)	3/427 (0.70%)
Abdominal pain lower [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Abdominal pain upper [†1]		
# participants affected / at risk	7/431 (1.62%)	10/427 (2.34%)
Aphthous stomatitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Breath odour [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Colitis [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Constipation [†1]		
# participants affected / at risk	5/431 (1.16%)	4/427 (0.94%)
Dental caries [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Diarrhoea [†1]		
# participants affected / at risk	7/431 (1.62%)	17/427 (3.98%)
Dry mouth [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Dyspepsia [†1]		
# participants affected / at risk	17/431 (3.94%)	6/427 (1.41%)
Eructation [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Flatulence [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Frequent bowel movements [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Gastritis [†1]		
# participants affected / at risk	5/431 (1.16%)	2/427 (0.47%)
Gastrooesophageal reflux disease [†1]		
# participants affected / at risk	4/431 (0.93%)	3/427 (0.70%)

Gastrooesophagitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Gingival pain [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Haematochezia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Haemorrhoids [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Inguinal hernia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Irritable bowel syndrome [†1]		
# participants affected / at risk	3/431 (0.70%)	3/427 (0.70%)
Mouth ulceration [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Nausea [†1]		
# participants affected / at risk	5/431 (1.16%)	9/427 (2.11%)
Oral pain [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Paraesthesia oral [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Parotid gland enlargement [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Peptic ulcer [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Proctitis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Rectal haemorrhage [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Stomach discomfort [†1]		
# participants affected / at risk	4/431 (0.93%)	1/427 (0.23%)
Stomatitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Tongue disorder [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Toothache [†1]		
# participants affected / at risk	3/431 (0.70%)	6/427 (1.41%)
Vomiting [†1]		
# participants affected / at risk	5/431 (1.16%)	6/427 (1.41%)
General disorders		
Asthenia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Chest discomfort [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Chest pain [†1]		
# participants affected / at risk	2/431 (0.46%)	4/427 (0.94%)

Fatigue [†1]		
# participants affected / at risk	6/431 (1.39%)	9/427 (2.11%)
Feeling hot [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Gravitational oedema [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Hypothermia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Influenza like illness [†1]		
# participants affected / at risk	1/431 (0.23%)	4/427 (0.94%)
Malaise [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Oedema peripheral [†1]		
# participants affected / at risk	4/431 (0.93%)	12/427 (2.81%)
Pain [†1]		
# participants affected / at risk	6/431 (1.39%)	9/427 (2.11%)
Pyrexia [†1]		
# participants affected / at risk	2/431 (0.46%)	5/427 (1.17%)
Swelling [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Thirst [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Hepatobiliary disorders		
Cholelithiasis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Immune system disorders		
Hypersensitivity [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Seasonal allergy [†1]		
# participants affected / at risk	2/431 (0.46%)	1/427 (0.23%)
Infections and infestations		
Alveolar osteitis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
American trypanosomiasis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Amoebiasis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Bronchitis [†1]		
# participants affected / at risk	4/431 (0.93%)	9/427 (2.11%)
Cellulitis [†1]		
# participants affected / at risk	2/431 (0.46%)	2/427 (0.47%)
Cystitis [†1]		
# participants affected / at risk	1/431 (0.23%)	4/427 (0.94%)
Diverticulitis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)

Ear infection [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Fungal skin infection [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Gastroenteritis [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Gastroenteritis viral [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Groin abscess [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Herpes zoster [†1]		
# participants affected / at risk	1/431 (0.23%)	3/427 (0.70%)
Infected bites [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Influenza [†1]		
# participants affected / at risk	10/431 (2.32%)	9/427 (2.11%)
Labyrinthitis [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Laryngitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Localised infection [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Lower respiratory tract infection [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Lymph gland infection [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Nail infection [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Nasopharyngitis [†1]		
# participants affected / at risk	19/431 (4.41%)	20/427 (4.68%)
Onychomycosis [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Oral herpes [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Osteomyelitis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Otitis externa [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Otitis media [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Otitis media acute [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Parasitic gastroenteritis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Pharyngitis [†1]		

# participants affected / at risk	4/431 (0.93%)	3/427 (0.70%)
Pharyngitis streptococcal [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Pyelonephritis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Pyoderma [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Rhinitis [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Sinusitis [†1]		
# participants affected / at risk	11/431 (2.55%)	10/427 (2.34%)
Sinusitis bacterial [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Tonsillitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Tooth abscess [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Tooth infection [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Upper respiratory tract infection [†1]		
# participants affected / at risk	14/431 (3.25%)	19/427 (4.45%)
Urinary tract infection [†1]		
# participants affected / at risk	7/431 (1.62%)	7/427 (1.64%)
Viral infection [†1]		
# participants affected / at risk	3/431 (0.70%)	4/427 (0.94%)
Viral pharyngitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Viral upper respiratory tract infection [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Vulvovaginal candidiasis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Vulvovaginal mycotic infection [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Vulvovaginitis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Wound infection [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Injury, poisoning and procedural complications		
Animal bite [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Arthropod bite [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Arthropod sting [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Back injury [†1]		

# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Burns second degree [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Contusion [†1]		
# participants affected / at risk	3/431 (0.70%)	7/427 (1.64%)
Device breakage [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Epicondylitis [†1]		
# participants affected / at risk	4/431 (0.93%)	0/427 (0.00%)
Excoriation [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Eye injury [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Fall [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Joint injury [†1]		
# participants affected / at risk	3/431 (0.70%)	0/427 (0.00%)
Joint sprain [†1]		
# participants affected / at risk	2/431 (0.46%)	2/427 (0.47%)
Limb crushing injury [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Limb injury [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Meniscus lesion [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Muscle injury [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Muscle strain [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Neck injury [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Post-traumatic pain [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Procedural pain [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Repetitive strain injury [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Rib fracture [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Skeletal injury [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Skin laceration [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Snake bite [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)

Thermal burn [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Tooth fracture [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Wrist fracture [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Investigations		
Alanine aminotransferase increased [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Aspartate aminotransferase increased [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Blood cholesterol increased [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Blood creatinine increased [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Blood potassium increased [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Blood pressure increased [†1]		
# participants affected / at risk	0/431 (0.00%)	4/427 (0.94%)
Blood urea increased [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Blood urine present [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Cardiac murmur [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Gamma-glutamyltransferase increased [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Heart rate irregular [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Hepatic enzyme increased [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Hepatitis C positive [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Weight increased [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Metabolism and nutrition disorders		
Diabetes mellitus [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Fluid retention [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Hypercholesterolaemia [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Hyperglycaemia [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Hyperlipdaemia [†1]		

# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Hypertriglyceridaemia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Increased appetite [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Polydipsia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Vitamin D deficiency [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Musculoskeletal and connective tissue disorders		
Arthralgia [†1]		
# participants affected / at risk	17/431 (3.94%)	25/427 (5.85%)
Arthritis [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Back pain [†1]		
# participants affected / at risk	20/431 (4.64%)	31/427 (7.26%)
Bone pain [†1]		
# participants affected / at risk	3/431 (0.70%)	0/427 (0.00%)
Bursitis [†1]		
# participants affected / at risk	6/431 (1.39%)	2/427 (0.47%)
Cervical spinal stenosis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Coccydynia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Costochondritis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Fibromyalgia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Flank pain [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Groin pain [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Intervertebral disc degeneration [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Joint stiffness [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Joint swelling [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Muscle spasms [†1]		
# participants affected / at risk	10/431 (2.32%)	5/427 (1.17%)
Muscular weakness [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Musculoskeletal chest pain [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Musculoskeletal pain [†1]		

# participants affected / at risk	7/431 (1.62%)	12/427 (2.81%)
Musculoskeletal stiffness [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Myalgia [†1]		
# participants affected / at risk	10/431 (2.32%)	9/427 (2.11%)
Neck pain [†1]		
# participants affected / at risk	7/431 (1.62%)	7/427 (1.64%)
Osteoarthritis [†1]		
# participants affected / at risk	7/431 (1.62%)	2/427 (0.47%)
Osteopenia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Pain in extremity [†1]		
# participants affected / at risk	18/431 (4.18%)	21/427 (4.92%)
Pain in jaw [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Periarthritis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Plantar fasciitis [†1]		
# participants affected / at risk	0/431 (0.00%)	3/427 (0.70%)
Rotator cuff syndrome [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Sacroiliitis [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Sensation of heaviness [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Spondyloarthropathy [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Synovial cyst [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Synovitis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Temporomandibular joint syndrome [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Tendon pain [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Tendonitis [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Melanocytic naevus [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Neoplasm [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Seborrhoeic keratosis [†1]		

# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Skin papilloma [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Thyroid neoplasm [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Nervous system disorders		
Carpal tunnel syndrome [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Cluster headache [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Dizziness [†1]		
# participants affected / at risk	8/431 (1.86%)	8/427 (1.87%)
Dysgeusia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Facial palsy [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Headache [†1]		
# participants affected / at risk	65/431 (15.08%)	68/427 (15.93%)
Hypoaesthesia [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Lethargy [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Lumbar radiculopathy [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Migraine [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Migraine with aura [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Neuropathy peripheral [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Paraesthesia [†1]		
# participants affected / at risk	2/431 (0.46%)	3/427 (0.70%)
Poor quality sleep [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Restless legs syndrome [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Sciatica [†1]		
# participants affected / at risk	1/431 (0.23%)	2/427 (0.47%)
Sinus headache [†1]		
# participants affected / at risk	2/431 (0.46%)	1/427 (0.23%)
Somnolence [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Syncope [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Tension headache [†1]		

# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Tremor † 1		
# participants affected / at risk	2/431 (0.46%)	1/427 (0.23%)
Psychiatric disorders		
Adjustment disorder † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Anxiety † 1		
# participants affected / at risk	4/431 (0.93%)	1/427 (0.23%)
Attention deficit / hyperactivity disorder † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Confusional state † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Depressed mood † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Depression † 1		
# participants affected / at risk	5/431 (1.16%)	3/427 (0.70%)
Disorientation † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Insomnia † 1		
# participants affected / at risk	11/431 (2.55%)	8/427 (1.87%)
Libido decreased † 1		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Nervousness † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Nightmare † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Restlessness † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Sleep disorder † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Stress † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Renal and urinary disorders		
Dysuria † 1		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Haematuria † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Hypertonic bladder † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Micturition frequency decreased † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Nephrolithiasis † 1		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Oliguria † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)

Pollakiuria [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Renal colic [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Renal pain [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Urine odour abnormal [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Reproductive system and breast disorders		
Adnexa uteri pain [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Breast mass [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Breast pain [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Dysmenorrhoea [†1]		
# participants affected / at risk	2/431 (0.46%)	4/427 (0.94%)
Erectile dysfunction [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Menorrhagia [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Menstrual disorder [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Uterine polyp [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Vulvovaginal dryness [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Respiratory, thoracic and mediastinal disorders		
Asthma [†1]		
# participants affected / at risk	4/431 (0.93%)	2/427 (0.47%)
Bronchial obstruction [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Chronic obstructive pulmonary disease [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Cough [†1]		
# participants affected / at risk	4/431 (0.93%)	4/427 (0.94%)
Dyspnoea [†1]		
# participants affected / at risk	3/431 (0.70%)	3/427 (0.70%)
Epistaxis [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Increased upper airway secretion [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Nasal congestion [†1]		
# participants affected / at risk	5/431 (1.16%)	3/427 (0.70%)
Nasal dryness [†1]		

# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Oropharyngeal pain [†1]		
# participants affected / at risk	7/431 (1.62%)	4/427 (0.94%)
Paranasal sinus hypersecretion [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Pharyngeal oedema [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Pleuritic pain [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Pulmonary congestion [†1]		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Rales [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Rhinitis allergic [†1]		
# participants affected / at risk	3/431 (0.70%)	2/427 (0.47%)
Rhinorrhoea [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Sinus congestion [†1]		
# participants affected / at risk	3/431 (0.70%)	2/427 (0.47%)
Wheezing [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Skin and subcutaneous tissue disorders		
Alopecia [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Blister [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Dermatitis [†1]		
# participants affected / at risk	0/431 (0.00%)	3/427 (0.70%)
Dermatitis allergic [†1]		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Dermatitis contact [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Eczema [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Eczema asteatotic [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Erythema [†1]		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Hair texture abnormal [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Hyperkeratosis [†1]		
# participants affected / at risk	0/431 (0.00%)	2/427 (0.47%)
Increased tendency to bruise [†1]		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Ingrown hair [†1]		

# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Pruritus † 1		
# participants affected / at risk	3/431 (0.70%)	2/427 (0.47%)
Rash † 1		
# participants affected / at risk	1/431 (0.23%)	7/427 (1.64%)
Rash erythematous † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Rash papular † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Rash pruritic † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Scar † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Seborrhoea † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Skin discolouration † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Urticaria † 1		
# participants affected / at risk	1/431 (0.23%)	1/427 (0.23%)
Surgical and medical procedures		
Myringoplasty † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Nail operation † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Tooth extraction † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Vasectomy † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Vascular disorders		
Flushing † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)
Hot flush † 1		
# participants affected / at risk	2/431 (0.46%)	0/427 (0.00%)
Hypertension † 1		
# participants affected / at risk	9/431 (2.09%)	13/427 (3.04%)
Systolic hypertension † 1		
# participants affected / at risk	1/431 (0.23%)	0/427 (0.00%)
Varicose vein † 1		
# participants affected / at risk	0/431 (0.00%)	1/427 (0.23%)

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (v11.1)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** Pfizer has the right to review disclosures, requesting a delay of < 60 days. Investigator will postpone single center publications until after disclosure of pooled data (all sites), < 12 months from study completion/termination at all participating sites. Investigator may not disclose previously undisclosed confidential information other than study results.

Results Point of Contact:

Name/Title: Pfizer ClinicalTrials.gov Call Center
Organization: Pfizer, Inc.
phone: 1-800-718-1021
e-mail: ClinicalTrials.govCallCenter@pfizer.com

No publications provided by Pfizer

Publications automatically indexed to this study:

Strand V, Simon LS, Dougados M, Sands GH, Bhadra P, Breazna A, Immitt J. Treatment of osteoarthritis with continuous versus intermittent celecoxib. J Rheumatol. 2011 Dec;38(12):2625-34. doi: 10.3899/jrheum.110636. Epub 2011 Nov 1.

Responsible Party:	Director, Clinical Trial Disclosure Group, Pfizer
ClinicalTrials.gov Identifier:	NCT00139776 History of Changes
Other Study ID Numbers:	**A3191173**
Study First Received:	August 29, 2005
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Last Updated:	June 24, 2009
Health Authority:	United States: Food and Drug Administration