Clinical trial results:
A randomized, double-blind, multi-center, placebo-controlled, parallel group study to evaluate the efficacy and safety of an etofenamate 5% (EFM) cutaneous patch applied twice daily in patients with acute uncomplicated unilateral ankle sprain for a period of 7 consecutive days.
Abbreviated title: Randomized, controlled, double-blind, multi-center trial to evaluate the efficacy and safety of an etofenamate 5% cutaneous patch vs. placebo in the treatment of acute uncomplicated unilateral ankle sprain

Summary

EudraCT number	2014-001720-30
Trial protocol	DE
Global end of trial date	23 April 2015

Results information

Result version number	v1 (current)
This version publication date	16 July 2016
First version publication date	16 July 2016

Trial information

Trial identification

Sponsor protocol code	DRO-200/II/14/1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Drossapharm AG
Sponsor organisation address	Birsweg 1, Arlesheim, Switzerland, 4144
Public contact	Dr. Roger Imboden, Drossapharm AG, 0041 61 705 10 00,
Scientific contact	Dr. Roger Imboden, Drossapharm AG, 0041 61 705 10 00,

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 September 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 April 2015
Global end of trial reached?	Yes
Global end of trial date	23 April 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy of an etofenamate 5% patch compared with placebo applied two times a day in patients with acute ankle sprains, in particular with regard to pain relief.

Protection of trial subjects:

Patients were monitored throughout participation in the study for occurrence of adverse events after drug administration (subjective tolerability) and the incidence of abnormal findings in measurements for objective tolerability: vital signs and physical findings (general and local).

Background therapy:

The Investigator provided rescue medication (paracetamol, 500 mg tablets) to the patient at the baseline visit. Patients were instructed to take the rescue medication provided for strong pain in the ankle or any other pain (e.g., headache) or fever (e.g., due to common cold) they might experience during the clinical trial only after previously consulting the Investigator. One or two tablets were allowed to be taken per day. No rescue medication was allowed within 6 hours immediately receding Visit 4 (48 h), Visit 5 (72 h) and Visit 6 (96 h).

Evidence for comparator:

Placebo patch indistinguishable from the investigational drug EFM 5% patch.

Actual start date of recruitment	08 November 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 80
Worldwide total number of subjects	80
EEA total number of subjects	80

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0

Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	80
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In total, 80 male and female adult patients with acute uncomplicated unilateral ankle sprainyears were enrolled from 4 study centers in Germany between November 2014 and April 2015. All enrolled patients were randomized to the study drugs ”etofenamate” or ”placebo”, respectively.

Pre-assignment

Screening details:

Patients with acute sprain (Injury within past 12 hours) of the lateral ankle, Grade I or II, were eligible for enrollment. Patients had to be randomized as soon as possible after the injury. The first study-related visit was the randomization visit during which the patient gave informed consent and inclusion and exclusion criteria were checked.

Period 1

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

Blinding implementation details:

The clinical trial was double-blind. Patients, Investigator staff, persons performing the assessments, monitors and data analysts remained blinded to the identity of the treatment from the time of randomization until database lock, using the following methods: (1) Randomization data kept strictly confidential, accessible only to authorized persons, (2) identity of the treatments was concealed by use of IMPs identical in packaging, labeling, schedule of administration, appearance, odor.

Arms

Are arms mutually exclusive?	Yes
Arm title	Etofenamate 5% patch

Arm description:

Etofenamate (EFM) 5% patch, batch number: 020913 (batch number blinded during labeling of the IMP as 120913).

Arm type	Experimental
Investigational medicinal product name	Etofenamate 5% patch
Investigational medicinal product code	EFM 5% patch
Other name	
Pharmaceutical forms	Cutaneous patch
Routes of administration	Topical use

Dosage and administration details:

1 patch applied 2 times a day. Duration of treatment 7 days.

Arm title	Placebo patch

Arm description:

Patients allocated to the comparator group received a matching placebo patch.

Arm type	Placebo
Investigational medicinal product name	Placebo patch
Investigational medicinal product code	Placebo
Other name	
Pharmaceutical forms	Cutaneous patch
Routes of administration	Topical use

Dosage and administration details:

1 patch applied 2 times a day. Duration of treatment 7 days.

Number of subjects in period 1	Etofenamate 5% patch	Placebo patch
Started	40	40
Completed	40	40

Baseline characteristics

Reporting groups	
Reporting group title	Etofenamate 5% patch
Reporting group description:	
Etofenamate (EFM) 5% patch, batch number: 020913 (batch number blinded during labeling of the IMP as 120913).	
Reporting group title	Placebo patch
Reporting group description:	
Patients allocated to the comparator group received a matching placebo patch.	

Reporting group values	Etofenamate 5% patch	Placebo patch	Total
Number of subjects	40	40	80
Age categorical			
Adults aged 18-60 (incl.) years were eligible for participation.			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	40	40	80
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Mean age by treatment grouop			
Units: years			
arithmetic mean	36.5	32	
standard deviation	± 12.8	± 11.6	-
Gender categorical			
Units: Subjects			
Female	17	21	38
Male	23	19	42
Pain on movement			
Measured in mm on a VAS (visual analogue scale).			
Units: mm			
arithmetic mean	79.3	80	
standard deviation	± 10.3	± 9.6	-
Pain at rest			
Measured in mm on a VAS (Visual analogue scale)			
Units: mm			
arithmetic mean	48.3	52.3	
standard deviation	± 25.3	± 23	-
Ankle swelling			
Swelling measured in cm, injured minus contralateral ankle.			
Units: cm			

arithmetic mean	2.1	1.9	
standard deviation	± 1	± 1	-

End points

End points reporting groups

Reporting group title	Etofenamate 5% patch
Reporting group description:	
Etofenamate (EFM) 5% patch, batch number: 020913 (batch number blinded during labeling of the IMP as 120913).	
Reporting group title	Placebo patch
Reporting group description:	
Patients allocated to the comparator group received a matching placebo patch.	

Primary: ankle pain-on-movement V5, change from baseline

End point title	ankle pain-on-movement V5, change from baseline
End point description:	
Ankle pain on movement was assessed in mm on a 100 mm visual analogue scale (VAS), 0 mm = 'no pain', and 100 mm = 'extreme pain'.	
End point type	Primary
End point timeframe:	
assessed by Visual Analogue Scale (VAS) at Visit 5 (72 hours after initiating treatment)	

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm				
arithmetic mean (standard deviation)	42.8 (± 19.2)	23.1 (± 18.3)		

Statistical analyses

Statistical analysis title	Change from baseline
Statistical analysis description:	
Analysis-of-covariance with treatment group and center as fixed effects and baseline POM assessment as a covariate.	
Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	20

Confidence interval	
level	95 %
sides	2-sided
lower limit	11.8
upper limit	28.3

Notes:
[1] - ANCOVA

Secondary: Pain on movement V4, change from baseline

End point title	Pain on movement V4, change from baseline
End point description:	
POM on VAS	
End point type	Secondary
End point timeframe:	
Visit 4 (48 hours after initiating treatment)	

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm				
arithmetic mean (standard deviation)	32.3 (± 15.5)	13.2 (± 12.4)		

Statistical analyses

Statistical analysis title	Absolute change from baseline to V4
Statistical analysis description:	
ANCOVA	
Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-19.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.5
upper limit	-13.2

Secondary: Pain on movement V6, change from baseline

End point title	Pain on movement V6, change from baseline
End point description: POM on VAS	
End point type	Secondary
End point timeframe: Visit 6 (96 hours after initiating treatment)	

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm				
arithmetic mean (standard deviation)	52.8 (± 19.5)	30.2 (± 21.4)		

Statistical analyses

Statistical analysis title	Difference between groups
Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-22.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32
upper limit	-13.9
Variability estimate	Standard deviation

Secondary: Pain on movement V7, change from baseline
End point title	Pain on movement V7, change from baseline
End point description: POM on VAS	
End point type	Secondary
End point timeframe: Visit 7 (Day 8 (±1))	

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm				
arithmetic mean (standard deviation)	70.4 (± 15.2)	50.1 (± 23.7)		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

POM on VAS at Visit 7 was compared between treatment groups using ANCOVA with terms in the model for treatment group, center [as fixed effects], and baseline POM assessment [as a covariate]. Least square mean for each treatment and the corresponding difference between least square means (EFM 5% - placebo) with the p-value and 95 % confidence interval will be presented from the specified ANCOVA model.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.3
upper limit	-13.6

Secondary: Pain at rest V5, change from baseline

End point title	Pain at rest V5, change from baseline

End point description:

Pain at Rest on VAS

End point type	Secondary

End point timeframe:

Visit 5 (72 hours after beginning of treatment).

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm				
arithmetic mean (standard deviation)	62.5 (± 17.8)	46 (± 20.3)		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

Pain at Rest at Visit 5 was compared between treatment groups using ANCOVA with terms in the model for treatment group, center [as fixed effects], and baseline POM assessment [as a covariate]. Least square mean for each treatment and the corresponding difference between least square means (EFM 5% - placebo) with the p-value and 95 % confidence interval were presented from the specified ANCOVA model.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-16.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.7
upper limit	-8.9

Secondary: AUC of POM 0-48h

End point title	AUC of POM 0-48h

End point description:

Area under the curve (AUC) of POM VAS pain scores. AUC was calculated using the trapezoidal rule.

End point type	Secondary

End point timeframe:

Over 0-48 hours.

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm x h				
arithmetic mean (standard deviation)	2791 (± 565.9)	3456 (± 467.3)		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

AUC over 0-48, 0-72 and 0-96 hours was compared between treatment groups using ANCOVA with terms in the model for treatment group, center [as fixed effects], and baseline POM assessment [as a covariate]. Least square mean for each treatment and the corresponding difference between least square means (EFM 5% - placebo) with the p-value and 95 % confidence interval were presented from the specified ANCOVA model.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Median difference (net)
Point estimate	-459.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-606.8
upper limit	-312

Secondary: AUC of POM 0-72h

End point title	AUC of POM 0-72h

End point description:

Area under the curve (AUC) of POM VAS pain scores. AUC was calculated using the trapezoidal rule

End point type	Secondary

End point timeframe:

Over 0-72 hours.

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm x h				
arithmetic mean (standard deviation)	4117.9 (± 863.4)	4872.3 (± 811.3)		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

AUC over 0-48, 0-72 and 0-96 hours was compared between treatment groups using ANCOVA with terms in the model for treatment group, center [as fixed effects], and baseline POM assessment [as a covariate]. Least square mean for each treatment and the corresponding difference between least

square means (EFM 5% - placebo) with the p-value and 95 % confidence interval were presented from the specified ANCOVA model.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (net)
Point estimate	-720.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1014.2
upper limit	-426.8

Secondary: AUC of POM 0-96h

End point title	AUC of POM 0-96h

End point description:

Area under the curve (AUC) of POM VAS pain scores. AUC was calculated using the trapezoidal rule.

End point type	Secondary

End point timeframe:

Over 0-96 hours.

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: mm x h				
arithmetic mean (standard deviation)	5034.3 (± 1151.3)	6171.3 (± 1173.7)		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

Area under the curve (AUC) of POM VAS pain scores over 0-48, 0-72 and 0-96 hours.
AUC over 0-48, 0-72 and 0-96 hours was compared between treatment groups using ANCOVA with terms in the model for treatment group, center [as fixed effects], and baseline POM assessment [as a covariate]. Least square mean for each treatment and the corresponding difference between least square means (EFM 5% - placebo) with the p-value and 95 % confidence interval were presented from the specified ANCOVA model.

Comparison groups	Etofenamate 5% patch v Placebo patch

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1092
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1521.6
upper limit	-663.3

Secondary: Swelling V5

End point title	Swelling V5

End point description:

Circumference measurement of swelling (compared to non-affected side) by "Figure of eight-method". Each ankle was measured three times and the average was calculated.

End point type	Secondary

End point timeframe:

At visit Visit 5

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: cm				
arithmetic mean (standard deviation)	0.9 (± 0.8)	1.1 (± 0.9)		

Statistical analyses

Statistical analysis title	Treatment effect

Statistical analysis description:

LS Means treatment effect (etofenamate minus placebo)

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANCOVA
Parameter estimate	Mean difference (net)

Confidence interval	
level	95 %
sides	1-sided

Secondary: Global efficacy V5, Q1

End point title	Global efficacy V5, Q1

End point description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)). Patients gave their opinion on the efficacy of the patch under double-blind conditions by response of 2 questions using the following 5-point scale for the question 1 (Q1): "Considering all the ways this treatment has affected you since you started in the clinical trial, how well are you doing?": 0 = very good, 1 = good, 2 = fair, 3 = poor and 4 = very poor; and following scale for question 2 (Q2): "How do you rate this medication as a treatment for the pain of ankle sprain?": 0 = excellent, 1 = very good, 2 = good, 3 = fair and 4 = poor.

End point type	Secondary

End point timeframe:

Visit 5

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: Number of patients (%)				
very good	7	6		
good	26	12		
fair	5	8		
poor	2	14		
very poor	0	0		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)). The global efficacy assessments were tested with the Cochran-Mantel-Haenszel (CMH) test of mean ridits stratified by site.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0021
Method	Cochran-Mantel-Haenszel

Secondary: Global efficacy V5, Q2

End point title	Global efficacy V5, Q2

End point description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)). Patients gave their opinion on the efficacy of the patch under double-blind conditions by response of 2 questions using the following 5-point scale for the question 1 (Q1): "Considering all the ways this treatment has affected you since you started in the clinical trial, how well are you doing?": 0 = very good, 1 = good, 2 = fair, 3 = poor and 4 = very poor; and following scale for question 2 (Q2): "How do you rate this medication as a treatment for the pain of ankle sprain?": 0 = excellent, 1 = very good, 2 = good, 3 = fair and 4 = poor.

End point type	Secondary

End point timeframe:

Visit 5

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: Number of patients (%)				
excellent	1	1		
very good	21	10		
good	14	14		
fair	3	8		
poor	1	7		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)). The global efficacy assessments were tested with the Cochran-Mantel-Haenszel (CMH) test of mean ridits stratified by site.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0322
Method	Cochran-Mantel-Haenszel

Secondary: Global efficacy V7, Q1

End point title	Global efficacy V7, Q1

End point description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)). Patients gave their opinion on the efficacy of the patch under double-blind conditions by response of 2 questions using the following 5-point scale for the question 1 (Q1): "Considering all the ways this treatment has affected you since you started in the clinical

trial, how well are you doing?": 0 = very good, 1 = good, 2 = fair, 3 = poor and 4 = very poor; and following scale for question 2 (Q2):
"How do you rate this medication as a treatment for the pain of ankle sprain?": 0 = excellent, 1 = very good, 2 = good, 3 = fair and 4 = poor.

End point type	Secondary

End point timeframe:

Visit 7

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: Number of patients (%)				
very good	14	10		
good	23	7		
fair	3	13		
poor	0	9		
very poor	0	1		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)). The global efficacy assessments were tested with the Cochran-Mantel-Haenszel (CMH) test of mean ridits stratified by site.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel

Secondary: Global efficacy V7, Q2

End point title	Global efficacy V7, Q2

End point description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)). Patients gave their opinion on the efficacy of the patch under double-blind conditions by response of 2 questions using the following 5-point scale for the question 1 (Q1): "Considering all the ways this treatment has affected you since you started in the clinical trial, how well are you doing?": 0 = very good, 1 = good, 2 = fair, 3 = poor and 4 = very poor; and following scale for question 2 (Q2):
"How do you rate this medication as a treatment for the pain of ankle sprain?": 0 = excellent, 1 = very good, 2 = good, 3 = fair and 4 = poor.

End point type	Secondary

End point timeframe:

Visit 7

End point values	Etofenamate 5% patch	Placebo patch		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	40		
Units: Number of patients (%)				
excellent	6	4		
very good	18	8		
good	12	11		
fair	4	7		
poor	0	10		

Statistical analyses

Statistical analysis title	Difference between groups

Statistical analysis description:

Global efficacy assessments at Visit 5 and 7 (72 hours after initiating treatment and Day 8 (±1)).
The global efficacy assessments weretested with the Cochran-Mantel-Haenszel (CMH) test of mean ridits stratified by site.

Comparison groups	Etofenamate 5% patch v Placebo patch
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0049
Method	Cochran-Mantel-Haenszel

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Throughout the study.

Adverse event reporting additional description:

The occurrence of adverse events was to be sought by non-directive questioning of the patient at each visit during the clinical trial. Adverse events also could have been detected when they were volunteered by the patient during or between visits or through physical examination or other assessments.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Etofenamate 5% patch

Reporting group description:

Etofenamate (EFM) 5% patch, batch number: 020913 (batch number blinded during labeling of the IMP as 120913).

Reporting group title	Placebo patch

Reporting group description:

Patients allocated to the comparator group received a matching placebo patch.

Serious adverse events	Etofenamate 5% patch	Placebo patch	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Etofenamate 5% patch	Placebo patch	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Rhinitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 January 2015	Modification of the expiry date of the Investigational Medicinal Product

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported