SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Traxam 3% w/w Gel

Felbinac 3% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Felbinac 3% w/w

Excipient(s) with known effect
Ethanol-300 mg/g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A clear non-greasy, non-staining gel containing 30mg felbinac in each gram.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prescription Only Medicine

This medicine is a topical anti-inflammatory and analgesic. It is indicated for the relief of rheumatic pain, pain of non-serious arthritic conditions and soft tissue injuries such as sprains, strains and contusions.

This medicine may be used as a coupling agent for ultrasound where both treatments are indicated.

4.2 Posology and method of administration

Posology

Rub 1g of this medicine (approximately 1 inch (2.5cm) of gel) into the affected area(s) 2 to 4 times a day. If symptoms do not resolve within 14 days, the patient should be reviewed.

The total daily dose should not exceed 25g per day irrespective of the number of affected areas.

Elderly: No special dosage recommendations are made for elderly patients.

Paediatric population

Safe use of this medicine in early childhood has not been established.

Method of administration

Topical application to affected area.

Hands should be washed following application of this medicine unless they are the treatment site.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory drugs.

4.4 Special warnings and precautions for use

Use of this medicine should be limited to intact and non-diseased skin. Contact with mucous membranes and the eyes should be avoided.

Discontinue if rash develops.

This medicine should not be applied with occlusive dressings at the same site as other topical preparations.

Topical application of large amounts may result in systemic effects, such as hypersensitivity, asthma and renal disease.

To avoid the possibility of photosensitivity, patients should be advised against excessive exposure to sunlight of treated areas.

Safe use of this medicine in early childhood has not been established.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

This medicine contains 300 mg of alcohol (ethanol) in each 1 g which is equivalent to 300 mg/g (30%w/w). It may cause burning sensation on damaged skin.

4.5 Interaction with other medicinal products and other forms of interaction

Felbinac is highly protein bound. However, serum levels following topical application are extremely low and therefore clinical drug interactions are unlikely.

Concurrent use of aspirin or other NSAIDs may result in an increased incidence of adverse reactions.

4.6 Fertility, pregnancy and lactation

Pregnancy and Breast-feeding

Since the safety of felbinac in human pregnancy and lactation has not been established, its use in these circumstances is not recommended. As with other non-steroidal anti-inflammatory agents which inhibit prostaglandin synthesis, dystocia and delayed parturition were observed when felbinac was administered simultaneously in animal studies.

Fertility

No human data available

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention: common (≥1/100, <1/10), rare (≥1/10,000, ≤1/1000), Not known (cannot be estimated from the available data).

The overall incidence of side effects reported with this medicine is low (less than 2%).

MedDRA System Organ Class	**Frequency**	**Undesirable Effects**
Immune system disorders	Rare	Hypersensitivity reactions such as widespread rashes (including urticaria) and bronchospasm
	Not known	Anaphylaxis
Nervous system disorders	Common	Paraesthesia which recover spontaneously upon cessation of treatment are the most common reactions.
Respiratory, thoracic and mediastinal disorders	Not known	Respiratory reactivity comprising asthma, aggravated asthma or dyspnoea
Gastrointestinal disorders	Rare	Gastrointestinal disturbances
Skin and subcutaneous tissue disorders	Common	Mild erythema, irritation, dermatitis, pruritis which recover spontaneously upon cessation of treatment are the most common reactions.
	Not known	Purpura, angioedema, bullous dermatoses (including epidermal necrolysis and erythema multiforme) and skin photosensitivity.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

If accidentally ingested, treatment should be symptomatic and supportive. Correction of severe electrolyte abnormalities should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain, ATC code: M02AA08

Felbinac is an anti-inflammatory/analgesic agent which has been developed into a topical gel for local treatment and pain and inflammation associated with conditions of the musculo-skeletal system.

5.2 Pharmacokinetic properties

Absorption

Clinical pharmacokinetic studies show that a topical dose of 10g of this medicine results in low circulating levels of felbinacin serum (600ng/ml). This is more than 20 times less than the levels recorded following oral administration of a single dose of 600mg fenbufen.

Distribution

Results of distribution studies demonstrate that felbinac is transferred preferentially to a site of inflammation when applied topically.

Biotransformation

The metabolism of felbinac is consistent with the known metabolic profile of fenbufen.

5.3 Preclinical safety data

Testing of biphenylacetic acid includes single and repeat dose studies, foetal toxicity and fertility studies, mutagenic and carcinogenic potential studies which show an acceptable toxicity profile for the active ingredient.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer

Diisopropanolamine

Ethanol (96%)

Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

1. Fluorovinyl resin-coated blind ended Aluminium Tubes with a plastic cap-

   18 months

2. LDPE/Aluminium Foil/LDPE laminate tubes with a plastic cap:

   18 months

3. Polyamide-imide or epoxyphenolic coated blind ended aluminium tubes with a plastic cap:

   18 months

4. In use shelf life – Once opened, use within 1 month

6.4 Special precautions for storage

Do not store above 25°C.

Keep the tube tightly closed

6.5 Nature and contents of container

This medicine is packed in fluorovinyl resin coated blind ended Aluminium Tubes with a Polypropylene cap, LDPE/Aluminium Foil/LDPE laminate tubes with a polypropylene cap or Polyamide-imide or epoxyphenolic coated blind ended aluminium tubes with a polypropylene cap.

Pack sizes: 50g, 100g (Prescription Only)

Not all pack sizes may be marketed

6.6 Special precautions for disposal

No special requirements for disposal

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Ltd,

Dashwood House,
69 Old Broad Street,
London, EC2M 1QS, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0085

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/03/2009

10 DATE OF REVISION OF THE TEXT

04 August 2015

10 DATE OF REVISION OF THE TEXT

21/02/2024