

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Traxam 3.17% w/w Cutaneous Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Felbinac 3.17 %w/w

Excipient: Contains approximately 3% w/w cetostearyl alcohol.
For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cutaneous Foam (foam)

A white semi-liquid foam.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the relief of symptoms associated with painful inflammatory conditions of the musculo-skeletal system such as:

Soft tissue traumas (sprains, strains and contusions).

Extra-articular rheumatic or inflammatory conditions including bursitis, capsulitis, frozen shoulder, myalgia, tendonitis, tenosynovitis and tennis elbow.

For the relief of pain and stiffness of rheumatic or non-serious arthritic conditions (i.e. common arthritis).

4.2 Posology and method of administration

Topical to affected area

Adults: The foam should be dispensed on to the hand and rubbed lightly into the affected area(s). Traxam is formulated to break down into a clear liquid when warmed by contact with the skin.

Gently rub a golf-ball sized quantity of foam (1½ inches or 4 cm in diameter) into the affected area(s) 2 to 4 times a day.

The total daily dose should not exceed 25g of foam irrespective of the number of affected areas; a golf ball size aliquot of foam weighs approximately 1g.

If symptoms do not resolve, it is advisable to review the patient to assess whether continued treatment is appropriate. Treatment should not extend beyond 6 weeks.

Elderly

No special dosage recommendations are made for elderly patients.

Children

Safe use of Felbinac in early childhood has not been established.

Hands should be washed following application of Traxam 3.17% w/w cutaneous Foam, unless they are the treatment site.

4.3 Contraindications

1. Use on broken skin or denuded skin.
2. Hypersensitivity to the ingredients. Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents.
3. Use with occlusive dressings.
4. Use simultaneously to the same site with any other topical preparations.
5. Use in the presence of local infection.

4.4 Special warnings and precautions for use

The total dose of product should not exceed 25g daily.

If there is no improvement, or the condition is aggravated, the doctor should be consulted.

The likelihood of systemic side effects occurring following the topical application of Traxam 3.17% w/w cutaneous Foam is very small compared to the frequency of side effects with oral NSAIDs, owing to low systemic absorption with felbinac (Traxam 3.17% w/w cutaneous Foam). This product should be used with caution in patients with a history of and /or active gastrointestinal ulceration or bleeding, or reduced cardiac, hepatic or renal function. Isolated cases of renal dysfunction have been reported.

The product should be withheld during active gastrointestinal ulceration/bleeding and used with caution in those with a past history of the same.

It is known that NSAIDs can interfere with platelet function. Although the likelihood of systemic side effects is very low, caution should be used in patients with active intracranial haemorrhage and bleeding diathesis or also recent or past history of the same.

It should only be used on non-diseased skin.

If sensitivity skin reactions occur, discontinue use.

Traxam 3.17% w/w cutaneous Foam should not be applied to skin wounds, infections or exfoliative dermatitis. It should not be allowed to come into contact with the eyes or mucous membranes.

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

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 therefore clinical drug interactions are unlikely.

However caution should be advised in patients receiving concomitant medications such as corticosteroids since theoretically this could increase the risk of gastrotoxicity or bleeding. Similarly there is a theoretical risk of enhanced effects of anticoagulants such as warfarin and anti-platelet against such as aspirin when used concomitantly with felbinac.

4.6 Fertility, pregnancy and lactation

As the safety of felbinac in human pregnancy and lactation has not been established, its use in these circumstances is not recommended. It is not known whether felbinac is transported into milk during lactation.

As with other non-steroidal anti-inflammatory agents which inhibit prostaglandin synthesis, dystocia and delayed parturition were observed when felbinac was administered subcutaneously in animal studies.

4.7 Effects on ability to drive and use machines

Non applicable.

4.8 Undesirable effects

The following convention has been utilised for the classification of undesirable effects: very common ($\geq 1/10$) common ($\geq 1/100, < 1/10$), uncommon ($\geq 1/1000, \geq 1/100$), rare ($\geq 1/10,000, \geq 1/1000$), very rare ($\geq 1/10,000$), unknown (cannot be estimated from the available data).

Nervous system disorder:
Very common- paraesthesia.

Respiratory thoracic and mediastinal disorder:
Rare - bronchospasm.

Gastrointestinal disorder:
Rare-gastrointestinal disturbances.

Skin and subcutaneous disorder:
Very common mild local erythema, irritation, dermatitis and pruritus.
Rare -hypersensitivity reaction as widespread rashes including urticaria.
Unknown- skin photosensitivity has been reported.

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 HPRRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

It is unlikely that Traxam 3.17% w/w cutaneous Foam would cause systemic effects even if accidental ingestion could occur. Consult your doctor, if ingestion is suspected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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

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

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

Similar low circulating levels of felbinac were achieved after administration of foam.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanolamine

Ethanol 96%

Purified Water

Cetomacrogol emulsifying wax containing cetostearyl alcohol and macrogol cetostearyl ether (22)

Macrogol 6 Glycerol Caprylocaprate

Butane 40

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

1 year.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate. Pressurised container. Protect from sunlight and do not expose to temperature exceeding 50°C.

Do not pierce or burn when empty. Do not spray or use near any ignition source (e.g. naked flame, open fire) or while smoking.

6.5 Nature and contents of container

A pressurised aerosol consisting of:

- A pressurised 100 g aluminium vial fitted with an aluminium microflex valve and diptube, containing a clear liquid and
- A foamhead type actuator for manual actuation.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharmaceuticals Ltd
Capital House
85 King William Street
London EC4N 7BL
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 899/19/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 October 1991
Date of last renewal: 14 October 2006

10 DATE OF REVISION OF THE TEXT

July 2015