Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Traxam 3% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains felbinac 3% w/w as the active ingredient.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
Product imported from UK:
A clear, smooth, non-greasy, non-staining topical gel.

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:
Rub 1g of Traxam 3%w/w Gel (approximately 1 inch (2.5cm) of gel) lightly into the affected area 2 to 4 times a day. If symptoms do not resolve, the patient should be reviewed to assess whether continued treatment is appropriate. The total dose should not exceed 25g a day, regardless of the number of affected areas. Treatment should not be extended beyond 6 weeks.

Elderly
No special dosage recommendations are made for elderly patients; however, NSAIDs should be used with particular caution in elderly patients who are more prone to adverse events. The lowest dose compatible with adequate safe clinical control should be employed. See also Section 4.4.

Paediatric Patient
There is insufficient information regarding the safety and efficacy of this medicine in children. It is not recommended for children under 18 yrs.

Hands should be washed following application of Traxam 3%w/w Gel, unless they are the treatment sites.

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.
6. Use in patients with active peptic ulceration.
7. Pregnancy and breast feeding.

4.4 Special warnings and precautions for use

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. Concomitant long term use of NSAIDs long-term, should undergo regular medical supervision to monitor for adverse events. Avoid contact with eyes and mucus membrane.

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. Although the systemic effects should be low, the drug should be used with caution in patients with renal, cardiac or hepatic impairment, history of peptic ulceration, inflammatory bowel disease or bleeding diathesis.

Elderly patients are particularly susceptible to the adverse effects of NSAIDs. Prolonged use of NSAIDs in the elderly is not recommended. Where prolonged therapy is required, patients should be reviewed regularly.

As NSAIDs can interfere with platelet function, they should be used with caution in patients with intracranial haemorrhage and bleeding diathesis.

It should only be used on non-diseased 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, therefore clinical drug interactions are unlikely.

4.6 Fertility, pregnancy and lactation

Pregnancy
Felbinac is suspected to cause serious birth defects when administered during pregnancy.
Traxam 3% w/w Gel is contraindicated (see section 4.3) in pregnancy. 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.

Lactation
Traxam 3% w/w Gel should not be used during breast-feeding. Traxam 3% w/w Gel is contraindicated during breastfeeding (see section 4.3).

4.7 Effects on ability to drive and use machines

Traxam 3% gel has no influence on ability to drive and use machine.

4.8 Undesirable effects

The overall incidence of side effects reported with Traxam 3%w/w Gel is low (less than 2%).

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

Nervous system disorder:
Very common - parasthesia.

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.

4.9 Overdose

It is unlikely that felbinac gel would cause adverse systemic effects, even if accidental ingestion should occur. Consult a doctor if ingestion is suspected.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: M02AA08

Felbinac is an anti-inflammatory/analgesic agent, which has been developed into a topical gel 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 Fenbufen.

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 fenbufen. In humans, FENBUFEN is almost completely absorbed after oral administration. It is metabolised to two main metabolites, HBPBA and BPAA, of which BPAA is the active compound. These are then further metabolised to other inactive compounds in the manner of cascade.

The elimination half-life of fenbufen and its metabolites is approximately 10-17 hours. FENBUFEN is excreted mainly by the kidney in the form of conjugated metabolites which are largely inactive.
Only about 4% of a dose is excreted as unchanged fenbufen, indicating extensive metabolism of the parent compound.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Carboxyvinylpolymer
Di-isopropanolamine
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25ºC. Keep the tube tightly closed.

6.5 Nature and contents of container

Overlabelled cardboard outer containing a 100g tube.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1151/81/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 26th September 2008

10 DATE OF REVISION OF THE TEXT

November 2012