

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Traxam Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Felbinac (Biphenylacetic Acid) 3.17% w/w

3 PHARMACEUTICAL FORM

Cutaneous foam (foam)

‘quick-break’ foam dispensed from cans which contain a concentrate of 3.17% felbinac in ethanol/aqueous vehicle with butane propellant.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Traxam Foam 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 injury such as sprains, strains and contusions.

4.2 Posology and method of administration

Prescription Only Medicine

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

Gently rub one golf ball sized (one and a half inches (4cm) in diameter) quantity of foam 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 1 gramme.

If symptoms do not resolve, it is advisable to review the patient to assess whether continued treatment is appropriate.

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 foam unless they are the treatment site.

Pharmacy Medicine

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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 1 gramme.

Do not use for longer than 7 days.

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

Children: Not recommended for use in children under 12 years of age.

Hands should be washed following application of Traxam Foam unless they are the treatment site.

4.3 Contraindications

Prescription Only Medicine

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

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Children under 12 years of age.

4.4 Special warnings and precautions for use

Use of Traxam Foam should be limited to intact skin. Contact with mucous membranes and the eyes should be avoided. Patients should avoid actuation of the aerosol can near their face or eyes.

Traxam Foam should not be applied with occlusive dressings or simultaneously to the same site as other topical preparations. It should only be used on non-diseased skin.

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

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.

4.6 Pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

A low incidence of mild local irritation, erythema, dermatitis, pruritis and paraesthesia which recovers spontaneously upon cessation of treatment may be expected with Traxam Foam.

Systemic side effects are rare; hypersensitivity reactions such as widespread rashes including urticaria and bronchospasm have been reported with felbinac. Gastrointestinal disturbances have been reported occasionally.

4.9 Overdose

It is unlikely that Traxam Foam 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

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 musculo-skeletal system.

5.2 Pharmacokinetic properties

Traxam Foam administered in a pharmacokinetic study achieves similar low circulating levels of felbinac to Traxam Gel.

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.

A primary dermal irritation study has shown Traxam Foam to be non-irritant and that it can be safely applied to human skin.

Traxam Foam is irritant to the eye but the irritation subsides within 7 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanolamine USNF
Ethanol 96% BP

Purified Water BP
Polawax A31
Softigen 767
Butane 40

6.2 Incompatibilities

None

6.3 Shelf life

12 Months

6.4 Special precautions for storage

Traxam Foam is packed in a pressurised canister. Protect the canister from sunlight and do not expose to temperatures above 50°C. Extremes of temperature can occur in motor cars. Do not pierce or burn canister even when empty. Do not refrigerate. Do not spray or use near any ignition source (e.g. naked flame, open fire) or while smoking.

Traxam Foam should be stored below 25°C.

6.5 Nature and contents of container

Aluminium monobloc can with white enamel body, double grinded microflex internal lacquer and colourless overlacquer. Cans are fitted with a valve made of aluminium microflex and diptube and shave foam actuator.

Pack sizes: 25g, 30g, (Pharmacy)

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

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd
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8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0086

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

01/11/2001 / 17/03/2003

10 DATE OF REVISION OF THE TEXT

10/02/2011