

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Traxam Gel - Prescription Only

Traxam Pain Relief Gel - Pharmacy Product

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Felbinac (Biphenylacetic Acid) 3% w/w

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

TRAXAM gel 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.

TRAXAM gel may be used as a coupling agent for ultrasound where both treatments are indicated.

Pharmacy Only Medicine

TRAXAM Pain Relief Gel 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.

4.2 Posology and method of administration

Prescription Only Medicine

Rub 1g Traxam Gel (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.

Children: Safe use of felbinac in early childhood has not been established.

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

Pharmacy Medicine

Rub 1g Traxam Gel (approximately 1 inch (2.5cm) of gel) into the affected area(s) 2 to 4 times a day. Do not use for longer than 7 days.

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

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 Gel 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.

Pharmacy 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. Children under 12 years of age.

4.4 Special warnings and precautions for use

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

Discontinue if rash develops.

Felbinac gel 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 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.

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

4.6 Pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The overall incidence of side effects reported with Traxam Gel is low (less than 2%). Local effects such as mild erythema, irritation, dermatitis, pruritis and paraesthesia, which recover spontaneously upon cessation of treatment are the most common reactions.

Anaphylaxis; respiratory reactivity comprising asthma, aggravated asthma or dyspnoea; purpura; angioedema; bullous dermatoses (including epidermal necrolysis and erythema multiforme) and skin photosensitivity have been reported.

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

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

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

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.

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

Carboxyvinyl Polymer

Diisopropanolamine

Ethanol (96%) BP

Purified Water BP

6.2 Incompatibilities

None.

6.3 Shelf life

1. Fluorovinyl resin-coated blind ended Aluminium Tubes with a plastic cap:
36 months
2. LDPE/Aluminium Foil/LDPE laminate tubes with a plastic cap:
24 months
3. Polyamide-imide or epoxyphenolic coated blind ended aluminium tubes with a plastic cap:
36 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Traxam Gel is packed in fluorovinyl resin-coated blind ended Aluminium Tubes with a plastic cap, LDPE/Aluminium Foil/LDPE laminate tubes with a plastic cap or Polyamide-imide or epoxyphenolic coated blind ended aluminium tubes with a plastic cap.

Pack sizes: 7.5g, 25g, 30g (Pharmacy)

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

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd

NLA Tower

12-16 Addiscombe Road

Croydon

CR0 0XT

United Kingdom

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

31/03/2009