

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen 5% gel,
Fenbid gel,
Phorpain Gel
Flexigel,
Boots Ibuprofen Gel, Ibuprofen Pain Relief Gel
Nurofen 5% gel,
Morrison's Ibuprofen pain relief 5% w/w gel
Ibucalm Ibuprofen Pain Relief Gel 5 % w/w
Ibuprofen Pain relief gel 5% w/w
Bell's Healthcare Ibuprofen 5% gel
Sainsbury's Ibuprofen 5% w/w gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5% w/w Ibuprofen Ph.Eur.

3 PHARMACEUTICAL FORM

Gel for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Pharmacy Only Indications:

Topical analgesic and anti-inflammatory for backache, pain of non-serious arthritic conditions, muscular pain, sprains, strains, sports injuries and neuralgia.

General Sales List Indications:

Topical analgesic and anti-inflammatory for backache, rheumatic and muscular pain, sprains, strains and sports injuries.

4.2 Posology and method of administration

Strength 5% maximum

Method of Administration

For topical application to the skin.

Dosage

Adults, the elderly and children over 14 years: Squeeze 50 to 125mg (4 to 10cm) of the gel from the tube and lightly rub into the affected area until absorbed. The dose should not be repeated more frequently than every four hours and no more than 4 times in any 24 hour period. Wash hands after each application. Do not exceed the stated dose. Review treatment after 2 weeks, especially if the symptoms worsen or persist.

Children under 14 years: Do not use on children under 14 years of age except on the advice of a doctor.

4.3 Contraindications

Hypersensitivity to any of the constituents. Hypersensitivity to aspirin, or other non-steroidal anti-inflammatory drugs, asthma, rhinitis or urticaria.

Not to be used on broken or damaged skin.

4.4 Special warnings and precautions for use

Apply with gentle massage only. Avoid contact with eyes, mucous membranes and inflamed or broken skin.

Discontinue if rash develops.

Hands should be washed immediately after use.

Not for use with occlusive dressings.

The label will state:

Do not exceed stated dose

Keep out of reach of children

For external use only.

If symptoms persist consult your doctor or pharmacist

Do not use if you are allergic to Ibuprofen or any of the ingredients, aspirin, or any other painkillers.

Consult your doctor or pharmacist before use if:

-you are taking aspirin or any other pain relieving medication

-you are pregnant

Not recommended for children under 14 years

Oral NSAIDs, including ibuprofen, can sometimes be associated with renal impairment, aggravation of active peptic ulcers, and can induce allergic bronchial reactions in susceptible asthmatic patients. Although the systemic absorption of topically applied ibuprofen is less than for oral dosage forms, these complications can occur in rare cases. For these reasons, patients with an active peptic ulcer, a history of kidney problems or asthma should seek medical advice before using Ibuprofen gel as should patients already taking other painkillers.

Patients should seek medical advice if symptoms worsen or persist.

Patients should be advised against excessive exposure to sunlight of area treated in order to avoid possibility of photosensitivity.

4.5 Interaction with other medicinal products and other forms of interaction

Non-steroidal anti-inflammatory drugs may interact with blood pressure lowering drugs, and may possibly enhance the effects of anticoagulants, although the chance of either of these occurring with a topically administered preparation is extremely remote. Concurrent aspirin or other NSAIDS may result in an increased incidence of adverse reactions.

4.6 Pregnancy and lactation

Not to be used during pregnancy or lactation.

Pregnancy:

Although no teratogenic effects have been demonstrated, ibuprofen should be avoided during pregnancy. The onset of labour may be delayed and the duration of labour increased.

Lactation:

Ibuprofen appears in breast milk in very low concentrations but is unlikely to affect breast fed infants adversely.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very rarely, susceptible patients may experience the following side effects with ibuprofen, but these are extremely uncommon when ibuprofen is administered topically. If they occur, treatment should be discontinued:-

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with ibuprofen. These may consist of (a) non-specific allergic reaction and anaphylaxis (b) respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritis, urticaria, purpura, angioedema and less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Gastro-intestinal: Side effects such as abdominal pain and dyspepsia have been reported.

Renal: Renal impairment can occur in patients with a history of kidney problems.

4.9 Overdose

Overdosage with a topical presentation of ibuprofen gel is unlikely.

Symptoms of severe ibuprofen overdose (eg following accidental oral ingestion) include headache, vomiting, drowsiness and hypotension. Correction of severe electrolyte abnormalities should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: M02A A13, Antiinflammatory preparations, non-steroids for topical use.

The gel is for topical application. It contains the active ingredient, ibuprofen, a phenylpropionic acid derivative which exerts its anti-inflammatory and analgesic effects directly in inflamed tissues underlying the site of application, mainly by inhibiting prostaglandin biosynthesis. Because it is formulated in an aqueous/alcoholic gel, the preparation also exerts a soothing and cooling effect when applied to the affected area

5.2 Pharmacokinetic properties

Specially formulated for external application, the active ingredient penetrates through the skin rapidly and extensively (approximately 22% of a finite dose within 48 hours), achieving high, therapeutically relevant local concentrations in underlying soft tissues, joints and the synovial fluid, whilst producing plasma levels that are unlikely to be sufficient to cause any systemic side-effects, other than in rare individuals who are hypersensitive to ibuprofen. Furthermore, there do not appear to be any appreciable differences between the oral and topical routes of administration regarding metabolism or excretion.

5.3 Preclinical safety data

There is no new data published on the active ingredient.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethylhydroxycellulose EP
Sodium Hydroxide EP
Benzyl alcohol EP
Isopropyl alcohol EP
Purified water EP

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25° C.

6.5 Nature and contents of container

Aluminium tube with internal epoxy phenolic coating containing 15g (trial size/starter pack) and 30/35/50/100g of Fenbid Gel. The 100g pack size is restricted to "Pharmacy" only.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Goldshield Group Limited

(trading as Goldshield Pharmaceuticals)

NLA Tower

12-16 Addiscombe Road

Croydon CR0 0X

8 MARKETING AUTHORISATION NUMBER(S)

PL 10972/0045

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26 April 1996

10 DATE OF REVISION OF THE TEXT

12/09/2011

