1 NAME OF THE MEDICINAL PRODUCT

Fenbid 10 %w/w Gel
Phorpain maximum strength 10% w/w Gel
Ibuprofen 10% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen Ph. Eur. 10% w/w Gel

Excipient(s) with known effects
Each 100mg of gel contains 1mg of Benzyl alcohol

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

A clear or slightly opalescent, colorless or almost colorless gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of pain and inflammation associated with backache, mild to moderate arthritic conditions, rheumatic and muscular pain, sprains, strains, sports injuries and neuralgia.

4.2 Posology and method of administration

Method of administration

For topical application to the skin.

Dosage

Adults, the elderly and children over 12 years: Squeeze 50 to 125mg (2 to 5cm) 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 12 years: Do not use on children 12 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.

Third trimester of pregnancy.

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 12 years.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen (see section 4.8). Most of these reactions occurred within the first month.

If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).

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.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

This medicine contains 1.25 mg benzyl alcohol in each 125mg dose which is equivalent to 0.01mg/mg. Benzyl alcohol may cause allergic reactions.

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.

There are no clinical data from the use of topical forms of Ibuprofen gel during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic Ibuprofen gel exposure reached after topical administration can be harmful to an embryo/fetus. During the first and second trimester of pregnancy, Ibuprofen gel should not be used unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors including Ibuprofen gel may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed. Therefore, Ibuprofen gel is contraindicated during the last trimester of pregnancy (see Section 4.3).

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, brochospasm 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.

Skin and subcutaneous tissue disorders:

- Very rare: Severe cutaneous adverse reactions (SCARs) (including Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis)
- Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), Acute generalised exanthematous pustulosis (AGEP), Photosensitivity reactions

Reporting of side effects
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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdosage with a topical presentation of Fenbid Forte Gel is unlikely.

Symptoms of severe ibuprofen overdosage (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, Anti-inflammatory 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

Hydroxyethyl cellulose EP
Sodium Hydroxide EP
Benzyl alcohol EP
Isopropyl alcohol BP
Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25ºC

6.5 Nature and contents of container

Collapsible aluminium tubes with internal protective lacquer with polypropylene screw caps.

100g

6.6 Special precautions for disposal

No special instructions

7 MARKETING AUTHORISATION HOLDER

Mercury Pharma Group Ltd,
Dashwood House, 69 Old Broad Street,
London, EC2M 1QS, UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 10972/0090

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/01/2025

10 DATE OF REVISION OF THE TEXT

14/01/2025