Phorpain Gel Maximum Strength

Summary of Product Characteristics Updated 17-Mar-2021 | ADVANZ Pharma

1. Name of the medicinal product

Fenbid Forte 10% Gel

Phorpain gel maximum strength

2. Qualitative and quantitative composition

Ibuprofen Ph. Eur. 10% Gel

Excipient(s) with known effect

Each 100mg of gel contains 1mg of Benzyl alcohol

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Gel for topical application

Clear or slightly opalescent, colourless or almost colourless gel with Isopropanol odour.

4. Clinical particulars

4.1 Therapeutic indications

Prescription Only indication

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.

Pharmacy Only indication

For the relief of pain and inflammation associated with backache, rheumatic and muscular pain, strains, sprains, neuralgia and sports injuries. For the relief of pain of non-serious arthritic conditions.

4.2 Posology and method of administration

Posology

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.

Paediatric population: Do not use on children 12 years of age, except on the advice of a doctor.

Method of administration

For topical application to the skin.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Hypersensitivity to aspirin, or other non-steroidal anti-inflammatory drugs.

Patients with 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 12 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.

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, which is equivalent to 0.01mg/mg. Benzyl alcohol may cause allergic reactions and mild local irritation.

This medicine contains less than 1 mmol sodium (23 mg) per 125mg, that is to say essentially 'sodium-free'.

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 Fertility, pregnancy and lactation

Not to be used during pregnancy or breast-feeding.

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.

Breast-feeding:

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

Fertility:

No data available

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention:

Uncommon (≥1/1,000 to <1/100)

Not known (frequency cannot be estimated from the available data)

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:

System Order Class	**Frequency**	**Adverse effects**
Immune system disorders	Uncommon	Hypersentivity[1]

Gastrointestinal disorders	Uncommon	Abdominal pain Dyspepsia
Renal and urinary disorders	Uncommon	Renal impairment[2]
Skin and subcutaneous tissue disorders	Not known	Photosensitivity reactions

[1]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).

[2]Renal impairment can occur in patients with a history of kidney problems.

Reporting of suspected adverse reactions

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 Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

Symptoms

Symptoms of severe ibuprofen overdosage (eg following accidental oral ingestion) include headache, vomiting, drowsiness and hypotension.

Management

Correction of severe electrolyte abnormalities should be considered.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory preparations, non-steroids for topical use.

ATC code: M02A A13

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

Absorption and Distribution

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.

Biotransformation and Elimination

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

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store below 25°C

6.5 Nature and contents of container

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

P: 30g, 50g

POM: 30, 50 & 100g

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7. Marketing authorisation holder

Mercury Pharma Group Ltd,

Capital House,

85 King William Street,

London EC4N 7BL, UK

8. Marketing authorisation number(s)

PL 10972/0082

9. Date of first authorisation/renewal of the authorisation

05/12/2005

10. Date of revision of the text

01/03/2021

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