

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen 5% gel,
Fenbid gel,
Phorpain Gel,
Flexigel,
Ibuprofen Pain relief gel 5% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

5% w/w Ibuprofen Ph.Eur.

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

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

Posology

Adults, the elderly and children over 12 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 USE MORE GEL THAN THE LABEL TELLS YOU TO.**

Review treatment after 2 weeks, especially if the symptoms worsen or persist.

Paediatric population: Do not use on children under 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.

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 USE MORE GEL THAN THE LABEL TELLS YOU TO.

Keep out of the sight and 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

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).

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.

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.

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)

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 ($\geq 1/1,000$ 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	Hypersensitivity ¹
Gastrointestinal disorders	Uncommon	Abdominal pain Dyspepsia
Renal and urinary disorders	Uncommon	Renal impairment ²
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	Photosensitivity reactions, Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP)

¹Hypersensitivity 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).

²Renal 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 the Yellow Card Scheme at: 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 ibuprofen 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

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

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

Aluminium tube with internal epoxy phenolic coating with Polypropylene cap containing 15g (trial size/starter pack) and 30/35/50/100g of Fenbid Gel/Phorpain Gel. The 100g pack size is restricted to "Pharmacy" only. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Mercury Pharma Group Ltd,
Dashwood House, 69 Old Broad Street,

London, EC2M 1QS, United Kingdom

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

25/01/2024