

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuprofen 10% w/w gel
Nurofen Joint & Back Pain Relief Max Strength 10 % Gel
Boots Max Strength Ibuprofen 10% Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 10% w/w
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

Gel.

For cutaneous use.

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of pain and inflammation associated with backache, rheumatic pain, muscular aches, pains or swellings such as sprains, strains and sports injuries.

4.2 Posology and method of administration

Posology

Adults, the elderly, and children over 12 years: Squeeze 2 to 5cm (i.e. 0.8 to 2 inches) of gel (50mg to 125 mg ibuprofen) from the tube and lightly rub into the affected area until absorbed. Use up to four times daily with individual doses administered at least 4 hours apart. Patients should not apply more than 500mg ibuprofen (approximately 5g gel) in any 24 hour period.

Wash hands after each application. 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 cutaneous use.

4.3 Contraindications

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

Hypersensitivity to aspirin, ibuprofen or related painkillers (including when taken by mouth), especially where associated with a history of 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.

Discontinue if rash develops.

Hands should be washed immediately after use.

Not for use with occlusive dressings.

Keep away from the eyes and mucous membranes.

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 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, asthma or intolerance to aspirin or ibuprofen taken orally should seek medical advice before using the gel as should patients already taking other painkillers.

The label should include the following warnings:

- Do not apply more of this medicine than the label tells you to.
- Not recommended for children under 12 years.
- Use this medicine only on your skin.
- Not to be used during pregnancy or breastfeeding.
- Do not use if you are allergic to any of the ingredients or have experienced problems with aspirin, ibuprofen or related painkillers (including when taken by mouth).

- If symptoms do not get better after 2 weeks or if they worsen, consult your doctor or pharmacist.
- Keep out of the sight and reach of children.
- Patients with asthma, an active peptic ulcer or history of kidney problems should consult their doctor before use, as should patients already taking aspirin or other painkillers.

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.

Where aspirin or other NSAID tablets are taken concurrently, it is important to bear in mind that these may increase the incidence of undesirable effects.

4.6 Fertility, Pregnancy and lactation

Not to be used during pregnancy or breastfeeding.

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).

Breastfeeding:

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 $< 1/100$)

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 Dyspepsis
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)
Renal and urinary disorders	Uncommon	Renal impairment ²

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 is extremely 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: M02AA13

Ibuprofen 10% w/w Gel is a topical preparation which has anti-inflammatory and analgesic properties. It contains the active ingredient, ibuprofen, which exerts its 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

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxyethyl cellulose E1525

Sodium Hydroxide E524

Benzyl alcohol E1519

Isopropyl alcohol

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

Keep the tube in the outer carton in order to protect from light.

6.5 Nature and contents of container

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

Pack Sizes: 30g and 40g.

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, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 10972/0089

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

04/12/2024

10 DATE OF REVISION OF THE TEXT

31/12/2025