

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Muscular Pain Relief Gel Pharmacy Only

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 gram of gel contains 50 mg of ibuprofen.

Excipients with known effects:

Benzyl alcohol – 1.25mg per dose

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel

Colourless or almost colourless, clear or slightly opalescent gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For cutaneous use.

Adults, the elderly and children over 12 years: Squeeze 50 to 125 mg (4 to 10 cm) 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 every application. Do not exceed the stated dose. Review treatment after 7 days, especially if the symptoms worsen or persist.

Children under 12 years: Do not use on children under 12 years of age except on the advice of a doctor.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1. In patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis or urticaria) in response to ibuprofen, acetylsalicylic acid (aspirin), or other non-steroidal anti-inflammatory drugs (NSAIDs).

Do not use in third trimester of pregnancy.

Not to be used on broken or damaged skin.

4.4 Special warnings and precautions for use

If symptoms persist for more than 7 days, or worsen at any time, consult your doctor or pharmacist.

Bronchospasm can occur in patients using ibuprofen who suffer or have previously suffered from bronchial asthma or allergic disease.

Discontinue immediately if rash develops.

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

Hands should be washed immediately after use.

Not for use with occlusive dressings.

The label will state:

Do not exceed the stated dose.

Keep out of the reach and sight 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.

Speak to a pharmacist or doctor before using this product if:

You are taking aspirin or any other pain relieving medication.

You are pregnant.

You have asthma.

Not to be used in children under 12 years, except on medical advice.

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, impaired hepatic function, a history of kidney problems or asthma should seek medical advice before using Ibuprofen gel as should patients already taking other painkillers.

For external use only.

Apply with gentle massage only.

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.

Excipients:

This medicine contains 1.25 mg benzyl alcohol in each dose.
Benzyl alcohol may cause allergic reactions and mild local irritation.

Severe cutaneous adverse reactions (SCARs):

Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and 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).

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 lactation.

Pregnancy:

There are no clinical data from the use of topical forms of Nurofen Muscular Pain Relief Gel Pharmacy Only during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic Nurofen Muscular Pain Relief Gel Pharmacy Only exposure reached after topical administration can be harmful to an embryo/fetus.

During the first and second trimester of pregnancy, Nurofen Muscular Pain Relief Gel Pharmacy Only 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 Nurofen Muscular Pain Relief Gel Pharmacy Only 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, Nurofen Muscular Pain Relief Gel Pharmacy Only is contraindicated during the last trimester of pregnancy (see Section 4.3).

During the last trimester of pregnancy there is a risk of premature closure of the foetal ductus arteriosus with possible persistent pulmonary hypertension. 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.

Fertility:

No observed effects at this level of exposure.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Systemic availability of topical ibuprofen is very low compared to orally administered NSAIDs. Adverse events, particularly those affecting the gastrointestinal tract, are less common with the use of topical ibuprofen.

The list of the following adverse effects relates to those experienced with topical ibuprofen at OTC doses (maximum 500 mg per day), in short-term use.

In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Adverse events which have been associated with ibuprofen are given below, tabulated by system organ class and frequency. Frequencies are defined as:

Very common ($\geq 1/10$); Common ($\geq 1/100$ and $< 1/10$); Uncommon ($\geq 1/1000$ and $< 1/100$); Rare ($\geq 1/10,000$ and $< 1/1000$); Very rare ($< 1/10,000$); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

Table of Adverse Events

System Organ Class	Frequency	Adverse Event
Immune System Disorders	Not known	Hypersensitivity ¹
Gastrointestinal Disorders	Not known	Abdominal pain, dyspepsia
Renal and Urinary Disorders	Not known	Renal impairment ²

In children ingestion of more than 400 mg/kg may cause symptoms. In adults the dose response effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Symptoms

Symptoms of Ibuprofen overdose include headache, vomiting, drowsiness and hypotension. Most patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea. Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma. Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

Management

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC code: M02AA13

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.

The systemic bioavailability reached through topical ibuprofen administration is about 5% of the level achieved through oral formulations.

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 relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxyethylcellulose
Sodium hydroxide
Benzyl alcohol
Isopropyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium tube with internal epoxy phenolic coating and polyethylene screw cap containing 100g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Ltd
Slough
SL1 4AQ

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0707

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/11/2024

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19/11/2024