SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Gel 5%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 gram of gel contains 50 mg of ibuprofen.
For the full list of excipients, see section 6.1
Excipients with known effects:
Benzyl alcohol – 1.25mg per dose

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, sports injuries.

4.2 Posology and method of administration

For cutaneous use.

Adults, the elderly and children over 14 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 14 years: Do not use on children under 14 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 urticarial) in response to ibuprofen, Acetylsalicylic acid (aspirin), or other non-steroidal anti-inflammatory drugs.

- 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

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.

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 14 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, 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.

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

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.

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 in animal experiments, ibuprofen should be avoided during pregnancy. During the last trimester of pregnancy there is a risk of premature closure of the fetal 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 (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥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]
General Disorders and Administration Site Conditions	Not known	Application site reaction [3]
Skin and subcutaneous tissue disorders	Not known	Photosensitivity reactions

Description of Selected Adverse Reactions

[1] Hypersensitivity reactions have been rarely reported following treatment with oral and topical ibuprofen. These may consist of (a) non-specific allergic reactions and anaphylaxis, (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely, exfoliative and bullous dermatoses (including toxic epidermal necrolysis and erythema multiform).

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

[3] The most common undesirable effects are application site reactions.

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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: https://sideeffects.health.gov.il

4.9 Overdose

Overdosage with a topical presentation is unlikely.

Symptoms of severe ibuprofen overdosage (e.g. following accidental oral ingestion) include headache, vomiting, drowsiness and hypotension. Correction of severe electrolyte abnormalities should be considered.
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

Ibuprofen is a non-steroidal anti-inflammatory drug which is effective as an analgesic and anti-inflammatory after both systemic and topical administration.

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

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Isopropyl alcohol
Ethylhydroxycellulose
Sodium hydroxide
Benzyl alcohol
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25^{o}C.

6.5 Nature and contents of container

Aluminium tube with polyethylene screw cap containing 50g.

6.6 Special precautions for disposal

No special requirements.

7. Manufacturer

Reckitt Benckiser Healthcare (UK) Ltd
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HU8 7DS
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8. Registration holder

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9. Registration Number

134 23 31074 00

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