Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nurofen 5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of gel contains 50mg ibuprofen (5% w/w)

Excipient with known effect:
One gram of gel contains 10mg benzyl alcohol (1% w/w)

For a full list of excipients, see 6.1

3 PHARMACEUTICAL FORM

Gel.

A clear, colourless and smooth gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For local symptomatic relief of pain and inflammation in the trauma of the tendons, ligaments, muscles and joints and in localised forms of soft tissue rheumatism.

4.2 Posology and method of administration

Posology:
Adults, the elderly and children over 12 years: Unscrew and invert cap to pierce seal. Apply a thin layer (1.0 to 2.5g) of gel to the affected area and massage gently until absorbed.

Leave four hours between doses and do not apply more than 4 times in any 24 hour period. Maximum daily dose is 10 g of gel, which equates to 500 mg ibuprofen.

Wash hands after each application. Do not exceed the stated dose.

The product should be applied according to the pack instructions for up to a maximum of 7 days. Seek medical advice if symptoms persist for more than one week.

Elderly: No special dose adjustment is necessary.

Children under 12 years: Do not use on children under 12 years of age.

Method of administration:
For topical application to the skin, short term use only.

4.3 Contraindications

Hypersensitivity to ibuprofen or to any of the excipients in the product.
In patients who have previously shown hypersensitivity reactions (e.g. bronchospasm, asthma, rhinitis, angioedema 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.

Children under 12 years

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Do not use in third trimester of pregnancy.

Not to be used on broken or damaged skin.

Children under 12 years.

4.4 Special warnings and precautions for use

Apply with gentle massage only. Avoid contact with eyes, lips, mucous membranes and inflamed or broken skin.
Discontinue immediately if rash develops.
Hands should be washed immediately after use.
Not for use with occlusive dressings.
Do not exceed the 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 before use if:
-You are taking aspirin or any other pain relieving medication
-You are pregnant

Not recommended for children under 12 years.

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) and acute generalised 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).

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

Topical NSAIDs have been associated with renal failure. The gel should be used with caution in patients with impaired renal function or a history of renal impairment.

Although the systemic availability of topical ibuprofen is low, the gel should still be used with caution in patients with impaired hepatic function.

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 or a history of peptic ulcer, intestinal inflammation or haemorrhagic diathesis should seek medical advice before using this product.

Patients should be advised against excessive exposure to natural or artificial light of area treated in order to avoid possibility of photosensitivity.

One gram of gel contains 10mg of benzyl alcohol (1% w/w). Benzyl alcohol may cause mild local irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Non-steroidal anti-inflammatory drugs may interact with antihypertensives, and may possibly enhance the effects of anticoagulants, however, if used correctly, the systemic transfer of ibuprofen is low, so that the interactions reported in association with oral ibuprofen are unlikely to occur.
Concurrent aspirin or other NSAIDs may result in an increased incidence of adverse reactions.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelets aggregation when they are dosed concomitantly. However, the limitations of these data and the uncertainties regarding the extra polation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional use (see section 5.1)

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no clinical data from the use of topical forms of ibuprofen during pregnancy. Even is systemic exposure is lower compared with oral administration, it is not known if the systemic ibuprofen exposure reached after topical administration can be harmful to an embryo/fetus. During the first and second trimester of pregnancy, Nurofen 5% w/w 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 Nurofen 5% w/w 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 Nurofen 5% w/w Gel is contraindicated during the last trimester of pregnancy (see section 4.3).

Breast feeding
In limited studies, ibuprofen appears in the breast milk in very low concentration and is unlikely to affect the breast fed infant 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 500mg 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.

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	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)

		Acute generalised exanthematous pustulosis (AGEP) 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 reaction and anaphylaxis, (b) respiratory tract activity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, (bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease) 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, Stevens-Johnson Syndrome and erythema multiforme).

[2]Renal impairment may occur following the use of topical ibuprofen, particularly in those with pre-existing renal dysfunction.

[3]The most frequently reported 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. Healthcare professionals are asked to report any suspected adverse reactions via
HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

Overdose with a topical presentation of Nurofen 5% Gel is unlikely.

In children excess ingestion of ibuprofen may cause symptoms including headache, vomiting, drowsiness and hypotension. In adults the dose response effect is less clear cut. The half-life in ibuprofen overdose is 1.5-3 hours.

Management should be symptomatic.

Symptoms of ibuprofen overdose include headache, vomiting, drowsiness and hypotension.
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

Ibuprofen is a non-steroidal anti-inflammatory drug which has been tested and proved to be effective as an analgesic, anti-pyretic and anti-inflammatory after systemic administration. When administered as a topical preparation, ibuprofen has been shown to be an effective topical analgesic and anti-inflammatory for the relief of mild to moderate arthritic pain, muscular pain, backache, sprains, strains, lumbago and fibrositis by virtue of percutaneous absorption.

The active product exerts its anti-inflammatory and analgesic effects directly in inflamed tissues underlying the site of application, mainly by inhibition of prostaglandin biosynthesis.

The product is formulated in an aqueous/alcoholic gel and exerts a soothing and cooling effect when applied to the affected area.

Experimental data suggest that ibuprofen may inhibit the effect of low dose aspirin on platelets aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400mg was taken within 8 h before or within 30 min after immediate release aspirin (81mg), a decreased effect of ASA on the formation of thromboxane or platelet aggregation occurred. However, the limitations of these data and the uncertainties regarding extrapolation of ex vivo data to the clinical situation imply that no firm conclusions can be made for regular ibuprofen use, and no clinically relevant effect is considered to be likely for occasional ibuprofen use.

5.2 Pharmacokinetic properties

Specially formulated for external application, the active ingredient penetrates through the skin achieving therapeutically relevant concentrations in underlying soft tissues, joints and the synovial fluid, whilst producing plasma levels that are unlikely to be sufficient to cause systemic effects, other than in rare cases of patient hypersensitivity to ibuprofen. After 24 hours an application to human skin shows that the dose administered is present in the epidermis and dermis.

Percutaneous absorption of this ibuprofen gel is approximately 5% that of oral ibuprofen. Therapeutic concentrations are reached locally; but not systemically.

There do not appear to be any differences between the oral and topical routes of administration regarding metabolism or excretion of ibuprofen.

5.3 Preclinical safety data

There are no preclinical data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydroxyethylcellulose
Sodium Hydroxide (E524)
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^{o}C.

6.5 Nature and contents of container

Aluminium tube with internal epoxy phenolic coating containing 30g or 50g of Nurofen 5% w/w Gel.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2000

Date of last renewal: 31st March 2010

10 DATE OF REVISION OF THE TEXT

July 2024