

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ibugel 5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 50 mg ibuprofen (5.0% w/w)

Excipients with known effect:

1g of gel contains 20 mg propylene glycol (E1520)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

Non-greasy, fragrance-free, clear aqueous-alcoholic gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the topical treatment of rheumatic and muscular pain, sprains, strains, backache and neuralgia. Ibugel is also indicated for symptomatic relief of pain due to non-serious arthritic conditions.

4.2 Posology and method of administration

Adults, including the elderly, and children over 12 years.

Apply the gel to the affected areas, up to three times daily, or as directed by the physician. On each occasion apply only enough gel to thinly cover the affected area, and gently massage well into the skin, until completely absorbed. Do not use excessively.

Treatment should be reviewed after 14 days and should not normally continue for more than a few weeks, unless recommended to do so by a doctor.

Ibugel is not normally recommended for use on children under the age of 12 years, unless instructed by their doctor.

4.3 Contraindications

Not to be used in cases of sensitivity to any of the ingredients.

Not to be used on broken skin.

Not to be used in asthmatic patients known to be hypersensitive to aspirin or other non-steroidal anti-inflammatory agents.

4.4 Special warnings and precautions for use

Seek medical advice if symptoms worsen or persist.

Oral NSAID's, 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, waterproof protective dressings should not be used over the treated areas, and patients with an active peptic ulcer, a history of kidney problems or asthma should seek medical advice before using Ibugel.

Propylene glycol may cause skin irritation.

Keep away from the eyes and mucous membranes.

This product should not be used with occlusive dressings.

4.5 Interaction with other medicinal products and other forms of interactions

Non-steroidal anti-inflammatory drugs may interact with blood pressure lowering drugs, and may enhance the effects of anticoagulants although the chance of either of these occurring with a topically administered preparation is extremely remote. Concurrent aspirin and other NSAIDs may result in an increased incidence of adverse reactions.

Experimental data suggest that oral ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. 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 (see section 5.1).

4.6 Fertility, pregnancy and lactation

Not to be used during pregnancy or lactation. 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. Ibuprofen appears in breast milk in very low concentrations, but is unlikely to affect breast fed infants adversely.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse drug reactions are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1,000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1,000$), very rare ($< 1/10,000$) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Immune System Disorders	Not known	Hypersensitivity ¹
Renal and urinary disorders	Not known	Renal impairment ²
Gastrointestinal disorders	Not known	Abdominal pain Dyspepsia
Skin and subcutaneous tissue disorders	Not known	Photosensitivity reactions Skin rash Pruritus Skin irritation

¹ *Hypersensitivity*: hypersensitivity reactions have been reported following treatment with 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, less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme).

² *Renal*: renal 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 HPRC Pharmacovigilance, Website: www.hpra.ie;

4.9 Overdose

Not applicable. Any overdose with a topical presentation of ibuprofen is extremely unlikely.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

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

ATC code: M02A A13

Ibugel 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, Ibugel also exerts a soothing and cooling effect when applied to the affected area.

Experimental data suggest that oral ibuprofen may inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. In one study, when a single dose of ibuprofen 400 mg was taken within 8 h before or within 30 min after immediate release aspirin dosing (81 mg), 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 rapidly and extensively, 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

Published information on subchronic toxicity studies confirms that topically applied ibuprofen is well tolerated both locally and by the gastro-intestinal tract. Any local erythema is only mild and no signs of mucosal lesions or ulcerogenic effects have been determined in the gastro-intestinal tract.

In the course of assessing mucosal tolerance, topical ibuprofen has been found to cause acute, but reversible, irritant reactions in the eyes and mucous membranes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Industrial methylated spirit (IMS)
Carbomer
Propylene glycol (E1520)
Diethylamine
Purified water

6.2 Incompatibilities

None known.

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

1) Membrane sealed, epoxy resin coated, collapsible aluminium tube, fitted with a screw cap, containing 30 g, 50 g or 100 g of product.

2) Membrane-sealed laminate tube, made of a HDPE/aluminium/Ethylene Acrylic Acid (EAA) copolymer, fitted with a cap, containing 30 g of product.

3) Laminate tube made of a HDPE/aluminium/Ethylene Acrylic Acid (EAA) copolymer, fitted with an air-return-free 'Precitube' pump head and cap, containing 30 g of product.

Not all pack sizes may be marketed.

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

Dermal Laboratories (Ireland) Limited
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Co Dublin
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8 MARKETING AUTHORISATION NUMBER

PA23128/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 September 1995

Date of last renewal: 19 September 2010

10 DATE OF REVISION OF THE TEXT

March 2021