# 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.
Do not use during pregnancy or lactation.

### 4.4 Special warnings and precautions for use

Seek medical advice if symptoms worsen or persist.
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 occur 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If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).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 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 interaction**

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.
There are no clinical data from the use of topical forms of ibuprofen during pregnancy. Even if 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 third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors including ibuprofen 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, 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 (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥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 |
|---|---|---|
| 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 | Photosensitivity reactions<br>Skin rash<br>Pruritus<br>Skin irritation<br>Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)<br>Acute generalised exanthematous pustulosis (AGEP) |
| Immune System Disorders | Not known | Hypersensitivity [1] |
| Renal and urinary disorders | Not known | Renal impairment [2] |
| Gastrointestinal disorders | Not known | Abdominal pain<br>Dyspepsia |

[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 HPRA 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
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

**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**

June 2024