1 NAME OF THE MEDICINAL PRODUCT

Ibuleve Max Strength Pain Relief 10% Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 10.0% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
Aqueous-alcoholic, non-greasy, fragrance-free, clear or slightly hazy.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For fast local relief of backache, rheumatic pain, muscular aches, pains or swellings such as sprains, strains and sports injuries.

4.2 Posology and method of administration

Adults, including the elderly, and children over 12 years

Lightly apply the gel to the affected areas and gently massage well into the skin, until completely absorbed. The dose is 0.5 to 1.25g gel (quantified on the labelling by appropriate means) up to three times daily with individual doses administered at least 4 hours apart. Patients should not apply more than approximately 4 g of gel (quantified appropriately on the labelling) in any 24 hour period. Wash hands after use unless treating them.

Unless recommended by a doctor, advice should be sought about continued treatment if symptoms persist for more than 2 weeks.

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

4.3 Contraindications

Not to be used if allergic to any of the ingredients, or in cases of hypersensitivity to aspirin, ibuprofen or related painkillers (including when taken by mouth), especially where associated with a history of asthma, rhinitis or urticaria.

Not to be used on broken or damaged skin.

Do not use during pregnancy or lactation.

4.4 Special warnings and precautions for use

Keep away from the eyes and mucous membranes.

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If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate).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 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 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, a history of kidney problems, asthma or intolerance to aspirin or ibuprofen taken orally should seek medical advice before using the gel.

Patients should seek medical advice if symptoms worsen or persist.

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.

4.5 Interaction with other medicinal products and other forms of interaction

Non-steroidal anti-inflammatory drugs may interact with blood pressure lowering drugs, although the chance of this occurring with a topically

administered preparation is extremely remote. Where aspirin or other NSAID tablets are taken concurrently, it is important to bear in mind that these may increase the incidence of undesirable effects.

4.6 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 (≥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 Skin rash Pruritus Skin irritation Drug reaction with eosinophilia and systemic symptoms

		(DRESS syndrome) 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 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Not applicable. Any overdose with a topical presentation of ibuprofen is extremely unlikely.
Symptoms of severe ibuprofen overdosage (eg following accidental oral ingestion) include headache, vomiting, drowsiness and hypotension.
Correction of severe electrolyte abnormalities should be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinflammatory preparations, non-steroids for topical use, ATC code: M02AA13.

Ibuleve Max Strength Pain Relief 10% Gel 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, Ibuleve Max Strength Pain Relief 10% Gel 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, achieving high, therapeutically relevant local concentrations in underlying soft tissues, joints and 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 of ibuprofen.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

IMS
Carbomers
Diethylamine
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months from the date of manufacture.

6.4 Special precautions for storage

Do not store above 25^{o}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, 40 g or 50 g of product).
2) Membrane-sealed collapsible aluminium tube, fitted with a screw cap (containing 30 g, 40 g or 50 g of product).

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

Diomed Developments Limited
T/A Dermal Laboratories
Tatmore Place, Gosmore
Hitchin, Herts SG4 7QR, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 0173/0404

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/06/2010

10 DATE OF REVISION OF THE TEXT

26/01/2024