SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Ibuleve Gel/Ibuleve Sports Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 5.0% w/w

Excipient with known effect:

1 g of gel contains 20 mg of propylene glycol (E 1520)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Administered topically for fast local relief of pain and inflammation in musculoskeletal conditions including backache, rheumatic and muscular pain, sprains, strains, lumbago and fibrositis, and neuralgia. Ibuleve is also indicated for symptomatic relief of pain due to non-serious arthritic conditions.

4.2 Posology and method of administration

Apply 1.0 to 2.5 g gel (quantified by appropriate means) to the affected areas, up to three times daily, or as directed by the physician. Individual doses should be administered at least 4 hours apart. On each occasion apply only enough gel to thinly cover the affected area, and gently massage well into the skin, until completely absorbed. The maximum daily dose is approximately 7.5 g of gel (quantified appropriately on the labelling) in any 24 hour period. Wash hands after use unless treating them. Do not use excessively.

Treatment should not normally continue for more than a few weeks, unless recommended to do so by a doctor.

The same dosage and dosage schedule applies to all age groups, although the gel is not normally recommended for children under 12 years, unless instructed by their 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 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, patients with asthma, an active peptic ulcer or a history of kidney problems, should seek medical advice before using the gel, as should patients already taking other painkillers.

Patients should seek medical advice if symptoms worsen or persist.

Propylene glycol may cause skin irritation.

Keep out of the sight and reach of children.

For external use only.

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, and may possibly enhance the effects of anticoagulants, although the chance of either of these 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 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 (≥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

Any overdose with a topical presentation of ibuprofen is extremely 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiinflammatory preparations, non-steroids for topical use, ATC code: M02A A13.

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

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

Carbomer

Propylene Glycol (E 1520)

Diethylamine

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 g, 40 g, 50 g and 100 g collapsible aluminium containers:- 3 years from the date of manufacture.

4 g collapsible aluminium containers:- 18 months from the date of manufacture.

30 g, 40 g, 50 g and 100 g laminate copolymer tubes:- 4 years from the date of manufacture.

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 4 g, 30 g, 40 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, 40 g, 50 g or 100 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, 40 g, 50 g or 100 g of product).

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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