1 NAME OF THE MEDICINAL PRODUCT

Ibuleve Pain Relief 5% Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ibuprofen 5.0% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray solution

Clear, colourless, fragrance-free, aqueous-alcoholic topical spray

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Adults, including the elderly, and children over 12 years

Holding the bottle upright or upside down, spray approximately 4 inches to 6 inches away from the skin. After every two to three sprays, gently massage the preparation into the skin, spreading the product over a wide area around the affected site. Apply 5 to 10 sprays (1 to 2ml) depending on the extent and severity of the condition. This amount may be repeated three to four times daily, with individual doses administered at least 4 hours apart. Patients should not apply more than 40 sprays (8ml) in any 24 hour period. Not to be used with occlusive dressings.

Hands should be washed 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 12 years of age 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

This product is flammable. Do not spray near flames, electric heaters or similar objects.

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.

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 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 the 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 should seek medical advice before using Ibuleve Pain Relief 5% Spray.

Keep away from the eyes and mucous membranes.

For external use only.

The label will include statements to the following effect:

If symptoms persist, consult your doctor or pharmacist.

Do not use if sensitive to any of the ingredients, particularly if asthmatic, suffer from rhinitis or urticaria and have previously shown hypersensitivity to aspirin, ibuprofen or related painkillers.

Patients with asthma, an active peptic ulcer or a history of kidney problems should seek medical advice before use, as should patients already taking aspirin or other painkillers.

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. Concurrent aspirin, ibuprofen or other NSAIDs may result in an increased 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 products 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: Anti-inflammatory preparations, non-steroids for topical use.

ATC code: M02A A13

Ibuleve Pain Relief 5% Spray 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 evaporative aqueous/alcoholic solution, Ibuleve Pain Relief 5% Spray 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 25% of a finite dose within 48 hours), 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

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

IMS

Macrogol 300

Macrogol cetostearyl ether (cetomacrogol)

Water, purified

6.2 Incompatibilities

None known

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25ºC

6.5 Nature and contents of container

High density polyethylene cylindrical bottles incorporating a controlled dose spray pump dispenser and overcap containing 35 ml, 50 ml or 100 ml 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
Hertfordshire SG4 7QR
UK

8 MARKETING AUTHORISATION NUMBER

PL 00173/0160

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/12/1994 / 11/06/2001

10 DATE OF REVISION OF THE TEXT

30/09/2025