

Product Summary

1. NAME OF THE MEDICINAL PRODUCT

IBUSPRAY

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

4.2 Posology and method of administration

Hold the bottle upright or upside down and spray approximately 4 inches to 6 inches away from the skin. After every 2 to 3 sprays, gently massage the preparation into the skin, spreading the product over a wide area around the affected site. The exact amount to be applied will vary, depending on the extent and severity of the condition, but it should normally be sufficient to apply 5 to 10 sprays (1 to 2 ml). This amount may be repeated three to four times daily, or more often if required. Do not use excessively.

Hands should be washed after use, unless treating them.

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 Ibuspray is not normally recommended for use on children below 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, particularly if asthmatic or suffer from rhinitis or urticaria, and have previously shown hypersensitivity to aspirin or ibuprofen or related painkillers.

Not to be used on broken 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 much less than from 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 Ibuspray.

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.

Consult your doctor before use if you are 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 this either of these occurring with a topically administered preparation is extremely remote. Concurrent aspirin or other NSAIDs may result in an increased incidence of undesirable effects.

4.6 Fertility, pregnancy and lactation

Do not use 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
Skin and subcutaneous	Very rare	Severe cutaneous

tissue disorders		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 unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC code: M02A A13

Ibuspray 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, Ibuspray 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

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

IMS
Macrogol 300
Macrogol cetostearyl ether (cetomacrogol)
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High density polyethylene cylindrical BOTTLES incorporating a controlled dose
SPRAY PUMP dispenser and OVERCAP (containing 35, 100 or 120 ml of product).
Supplied as original packs.

6.6 Instruction for use and handling

Not applicable

Administrative Data

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

PL 00173/0150

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

23 September 1993

10. DATE OF REVISION OF THE TEXT

26/01/2024