

PRESCRIBING INFORMATION

Ibuprofen 10% Gel

Presentation: Topical gel containing 10% w/w ibuprofen.

Indications: For the relief of pain and inflammation associated with backache, mild to moderate arthritic conditions, rheumatic and muscular pain, sprains, strains, sports injuries and neuralgia

Dosage and Administration: For topical application. *Adults, the elderly and children over 12 years:* Squeeze 50 to 125mg (2 to 5cm) of the gel from the tube and lightly rub into the affected area until absorbed. The dose should not be repeated more frequently than every four hours and no more than 4 times in any 24-hour period. *For children under 12 years:* Do not use on children under 12 years of age.

Contraindications: Hypersensitivity to any of the constituents. Hypersensitivity to aspirin, or other non-steroidal anti-inflammatory drugs, asthma, rhinitis or urticaria. Not to be used on broken or damaged skin. Third trimester of pregnancy.

Precautions and warnings: Apply with gentle massage only. Avoid contact with eyes, mucous membranes and inflamed or broken skin. Discontinue if rash develops. Wash hands immediately after use. Not for use with occlusive dressings. Do not use if allergic to ibuprofen or any of the ingredients, aspirin, or any other painkillers. Not recommended for children under 12 years. 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. Complications can occur in rare cases. Patients should seek medical advice if symptoms worsen or persist. Patients should be advised against excessive exposure to sunlight of area treated in order to avoid possibility of photosensitivity.

Interactions: Blood pressure lowering drugs and may enhance the effects of anti-coagulants. Concurrent aspirin or other NSAIDs may result in an increased incidence of adverse reactions.

Pregnancy and lactation: Not to be used during pregnancy or lactation.

Undesirable effects: *Serious:* Very rarely, susceptible patients may experience the following side effects with ibuprofen, but these are extremely uncommon when ibuprofen is administered topically. Hypersensitivity reactions such as non-specific allergic reaction and anaphylaxis, respiratory tract reactivity comprising of asthma, aggravated asthma, bronchospasm or dyspnoea, assorted skin disorders, including rashes of various types, pruritis, urticaria, purpura, angioedema and less commonly, bullous dermatoses (including epidermal necrolysis and erythema multiforme). If they occur, treatment should be discontinued. Renal impairment can occur in patients with a history of kidney problems.

(Please refer to the Summary of Product Characteristics for detailed information)

Overdose: Overdosage with a topical presentation of ibuprofen gel is unlikely. Symptoms of severe ibuprofen over dosage (following oral ingestion) include headache, vomiting, drowsiness and hypotension. Correction of severe electrolyte abnormalities should be considered.

Legal Category: POM: 30, 50 & 100g; P: 30g, 50g

Basic NHS Costs: £5.50 (100g)

Marketing Authorisation Numbers: PL 10972/0090

Marketing Authorisation Holder: Mercury Pharma Group Ltd Dashwood House, 69 Old Broad Street, London, EC2M 1QS, UK **Date of preparation:** April 2024 [UK/FEN/PM/0008]

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to **Advanz Pharma Medical Information** via telephone on +44 0 8700 70 30 33 or via e-mail at medicalinformation@advanzpharma.com