

Prescribing Information: Powergel (ketoprofen) 2.5% gel.

Please consult the Summary of Product Characteristics (SmPC) for full prescribing information.

Presentation: Gel containing 2.5g/100g of ketoprofen. Also contains citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool.

Use: For local relief of pain and inflammation with soft tissue injuries and acute strains and sprains in adults.

Dosage and administration: Adults and elderly: Applied topically to the affected area two or three times daily. Maximum duration of use should not exceed 10 days. Paediatric population: Not recommended for children under 12 years. Powergel should be applied with gentle massage only. Apply 5 to 10 cm of gel with each application.

Contraindications: Hypersensitivity to the active substance or to any of the excipients. History of any photosensitivity reaction. Known hypersensitivity reactions to fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAIDs. History of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate or UV blocker or perfumes. Sun exposure during treatment and 2 weeks after discontinuation. Application to open or infected wounds or lesions of the skin, or near the eyes. Third trimester of pregnancy.

Warnings and Precautions: Use with caution in patients with reduced heart, liver or renal function. The topical use of large amounts may give rise to systemic effects. Treatment should be discontinued if rash or skin reaction occur. Wash hands after application. Avoid exposure of treated area to direct sunlight during treatment and for two weeks after treatment. Do not use with occlusive dressings. Avoid contact with mucous membranes.

Interactions: Interactions are unlikely due to topical use. However, advisable to monitor patients under treatment with coumarinic substances.

Pregnancy and lactation: Use during the first and second trimester should be avoided. Contraindicated during the third trimester. Not recommended during breast feeding.

Side-effects: The most common adverse reactions are photosensitive reactions with the majority occurring due to exposure of skin to sunlight before 15 days from the last application. Uncommon ($\geq 1/1000$ to $< 1/100$): Rash, eczema, pruritus, burning sensation, application site burn. Rare ($\geq 1/10\ 000$ to $< 1/1000$): Dermatitis, urticarial, blister, photosensitivity reaction, photosensitivity allergic reaction, skin exfoliation, skin oedema. Very rare ($< 1/10\ 000$): Acute renal failure, insufficiency aggravated. Not known: Secondary impetigo, eosinophilia, anaphylactic reaction, angioedema, hypersensitivity, eyelid oedema, vasculitis, peptic ulcer, gastrointestinal bleeding, diarrhoea, lip oedema, pyrexia, wound complication.

Package quantities and price: 50g £3.06. 100g £5.89.

Legal category: POM.

Marketing Authorisation Holder: A Menarini Industrie Farmaceutiche Riunite S.r.l

Marketing authorisation numbers: PL 10649/0001

Marketed by: A. Menarini Farmaceutica Internazionale SRL.

Further information is available on request to A. Menarini Farmaceutica Internazionale SRL, Menarini House, Mercury Park, Wycombe Lane, Wooburn Green, Buckinghamshire, HP10 0HH, UK or may be found in the SmPC.

Last updated: July 2021

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to A. Menarini Farmaceutica Internazionale SRL. Phone no. 0800 085 8678 or email: menarini@medinformation.co.uk