SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

POWERGEL 2.5% gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Powergel contains ketoprofen BP 2.5g/100g.

Excipients with known effect: citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool.

1 g gel contains 307 mg ethanol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

Gel of mucilaginous consistency, colourless or slightly yellowish, almost transparent, with an aromatic odour for topical application.

4.1 Therapeutic indications

For local relief of pain and inflammation associated with soft tissue injuries and acute strains and sprains.

Powergel is indicated in adults.

4.2 Posology and method of administration

Posology

Powergel should be applied topically to the affected area two or three times daily. Maximum duration of use should not exceed 10 days.

Paediatric population

Not recommended in children under 12 years of age. The safety and efficacy of ketoprofen gel in children have not been established.

Method of administration

For cutaneous use.

Powergel should be applied with gentle massage only.

Tube or dispenser: Apply 5 to 10cm of gel (100-200mg ketoprofen) with each application; for the pump dispenser push the pump 3-6 times.

4.3 Contraindications

- Known hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- History of any photosensitivity reaction.
- Known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis or urticaria 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, even in case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation (see section 4.4).
- Ketoprofen gel should not be applied to open or infected wounds or lesions of the skin, such as occurs, for example, with eczema or acne, or near the eyes.
- Third trimester of pregnancy (see section 4.6).

4.4 Special warnings and precautions for use

- The gel should be used with caution in patients with reduced heart, liver or renal function: isolated cases of systemic adverse reactions affecting renal function have been reported.
- The topical use of large amounts of product may give rise to systemic effects such as hypersensitivity and asthma.
- The treatment should be interrupted if rash appears.
- The recommended length of treatment should not be exceeded due to the risk of developing contact dermatitis and photosensitivity reactions increases over time.
- Hands should be washed thoroughly after each application of the product.
- Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of octocrylene containing products.
- It is recommended to avoid exposure of treated skin to direct sunlight including solarium (sunbeds), and to protect treated areas by wearing clothing during treatment with the product and for two weeks following its discontinuation to avoid the risk of photosensitisation.
- Do not use with occlusive dressings.
- The gel must not come into contact with mucous membranes and with the eyes.
- Patients with asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis have a higher risk of allergy to aspirin and/or NSAIDs than the rest of the population.
- The use of topical products, especially if it is prolonged, may give rise to phenomena of sensitisation or local irritation.
- The excipients citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool may cause allergic reactions.
- Ethanol may cause a burning sensation on damaged skin.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions are unlikely as serum concentrations following topical administration are low. It is, however, advisable to monitor patients under treatment with coumarinic substances.

4.6 Fertility, pregnancy and lactation

Pregnancy

During the first and second trimester:

There are no clinical data from the use of topical forms of ketoprofen during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic ketoprofen exposure reached after topical administration can be harmful to an embryo/fetus. During the first and second trimester of pregnancy, ketoprofen should not be used unless clearly necessary. If used, the dose should be kept as low and duration of treatment as short as possible.

During the third trimester of pregnancy:

During the third trimester of pregnancy, systemic use of prostaglandin synthetase inhibitors including ketoprofen may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy prolonged bleeding time in both mother and child may occur, and labour can be delayed. Therefore, ketoprofen is contraindicated during the last trimester of pregnancy (see Section 4.3)

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

The most common adverse reactions are photosensitive reactions (phototoxic and photosensitivity allergic reactions), the majority of which occurs after an incorrect use of the product (exposure of the skin to sunlight or solarium before 15 days from the last application, see sections 4.3 and 4.4). There have been reports of localised skin reactions due to photosensitivity, including erythema, pruritus and burning sensations, which might spread beyond the area of application. Cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized have occurred rarely.

Other systemic effects of anti-inflammatory drugs: hypersensitivity, gastrointestinal and renal disorders (these depend on the transdermic spreading of the active ingredient, hence on the amount of gel applied, on the surface involved, on the degree of intactness of the skin, on the duration of the treatment and on the use of occlusive bandages).

Since marketing, the following adverse reactions have been reported. They have been listed according to classes of organ and system and classified according to their frequency as follows: very common (≥1/10); common (≥1/100 to <1/10), uncommon

(≥1/1000 to <1/100); rare (≥1/10000 to <1/1000); very rare (<1/10000); not known (the frequency cannot be established based on the available data).

System Organ Class	**Uncommon**	**Rare**	**Very rare**	**Not known**
Infections and infestations				Secondary impetigo
Blood and lymphatic system disorders				Eosinophilia
Immune system disorders				Anaphylactic reactions, including anaphylactic shock, angioedema, hypersensitivity reactions
Eye disorders				Eyelid oedema
Vascular disorders				Vasculitis
Gastrointestinal disorders				Peptic ulcer, gastrointestinal bleeding, diarrhoea, lip oedema
Skin and subcutaneous tissue disorders	Localised skin reactions such as erythema, eczema, pruritus and burning sensation	Dermatitis (allergic, bullous, contact, exfoliative, vesicular), urticaria, blister, photosensitivity reaction, photosensitivity allergic reaction, skin exfoliation, skin oedema		
Renal and urinary disorders			New cases or worsening of existing cases of renal insufficience.	
General				Pyrexia

disorders and administration site conditions				
Injury, poisoning and procedural complications				Wound complication

Elderly patients are particularly susceptible to the adverse effects of non-steroidal anti-inflammatory drugs.

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. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose is unlikely to be caused by topical administration. If accidentally ingested, the gel may cause systemic adverse effects depending on the amount ingested. However, if they occur, treatment should be symptomatic and supportive in accordance with overdosage of oral anti-inflammatories.

5.1 Pharmacodynamic properties

Pharmacotherapeutic category: non-steroid anti-inflammatory drug for topical use.

ATC code: MO2AA10

Mechanism of action

Ketoprofen is an inhibitor of both the cyclo-oxygenase and lipoxygenase pathways. Inhibition of prostaglandin synthesis provides for potent anti-inflammatory, analgesic and antipyretic effects. Lipoxygenase inhibitors appear to attenuate cell-mediated inflammation and thus retard the progression of tissue destruction in inflamed joints. In addition, Ketoprofen is a powerful inhibitor of bradykinin (a chemical mediator of pain and inflammation), it stabilises lysosomal membranes against osmotic damage and prevents the release of lysosomal enzymes that mediate tissue destruction in inflammatory reactions.

5.2 Pharmacokinetic properties

Absorption

By cutaneous route, absorption is very low. The percutaneous application of 50-150 mg of ketoprofen produces plasma levels of the active ingredient of 0.08-0.15 µg/mL approx. 5-8 hours after application.

Powergel allows the site specific topical delivery of ketoprofen with very low plasma concentrations of drug. Therapeutic levels in the affected tissues provide relief from pain and inflammation, yet will satisfactorily overcome the problem of significant systemic unwanted effects.

Distribution

After oral administration of a single dose, maximum blood concentrations are achieved within 2 hours.Ketoprofen plasma half-life ranges from 1 to 3 hours. Plasma protein binding is 60%-90%.

Elimination

Elimination is mainly by urinary route and in glucuronated form; approximately 90% of the amount administered is excreted within 24 hours.

5.3 Preclinical safety data

In animal trials no embryopathic effects have been found, while there is no epidemiological evidence of the safety of ketoprofen in human pregnancy. In preclinical and clinical trials on Ketoprofen no serious adverse effects have been observed, although anecdotal cases of systemic adverse reactions have been described. There are no preclinical data of relevance to the prescriber which are additional to that already included in other parts of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer

Ethanol

Neroli fragrance (containing citral, citronellols, farnesol, gerianol, d-limonene and linalool)

Lavandin fragrance (containing coumarin, gerianol, d-limonene and linalool)

Triethanolamine

Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Tube: 60 months.
Dispenser: 36 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Soft aluminium tube, treated inside with non-toxic epoxy resin:
30g sample pack, 50g pack, 2x50g twin pack, 100g pack

Dispenser: rigid polypropylene dispenser containing 50g or 100g gel.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

A Menarini Industrie Farmaceutiche Ruinite S.r.l.

Via Sette Santi, 3

50131 Florence

Italy

8 MARKETING AUTHORISATION NUMBER(S)

PL 10649/0001.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 January 1993

Date of latest renewal: 1 May 2008

10 DATE OF REVISION OF THE TEXT

30/01/2024