Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Fastum 2.5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fastum Gel contains Ketoprofen 2.5% w/w.

Excipients with known effect: citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool. 1 g gel contains 320 mg ethanol 96%.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.
A colourless or slightly yellowish, non-greasy, non-staining gel with an aromatic fragrance for cutaneous use.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For local relief of pain and inflammation associated with rheumatic and muscular disorders and soft tissue injuries such as acute strains and sprains.

Fastum Gel is indicated in adults.

4.2 Posology and method of administration

Posology
Fastum Gel should be applied topically to the affected area two or three times daily. Maximum duration of use should not exceed 10 days.
The lowest dose compatible with adequate safe clinical control should be employed in the elderly, who are more prone to adverse events.

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.
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. After application gel should be rubbed well to ensure local absorption of ketoprofen.

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 pathological skin changes such as eczema or acne or on infected skin, open wounds, lesions of the skin.
- Third trimester of pregnancy (see section 4.6).

4.4 Special warnings and precautions for use

- Although systemic effects should be low, ketoprofen should be used with caution in patients with severe renal impairment, or reduced cardiac, hepatic or renal function, history of peptic ulceration or inflammatory bowel disease or bleeding diathesis. Isolated cases of systemic adverse reactions consisting of renal dysfunction have been reported.

- Topical application of large amounts may result in systemic effects, including 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 increasing 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 protect treated areas by wearing clothing during treatment with the product and for two weeks following its discontinuation to avoid the risk of photosensitisation.
- Not for use with occlusive dressing.
- The gel must not come into contact with mucous membranes or 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 total dose of product should not exceed 25g daily.

If there is no improvement, or the condition is aggravated the doctor should be consulted.

The excipients citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool may cause allergic reactions.

Ethanol may cause 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. Serious interactions have been recorded after use of high dose methotrexate with non-steroidal anti-inflammatory agents, including ketoprofen, when administered by the systemic route. It is advisable to monitor patients under treatment with coumarinic substances.

4.6 Fertility, pregnancy and lactation

As there has been no such experience with the topical formulation, the following is stated according to the systemic formulation:

Pregnancy
In mice and rats, there is no evidence of teratogenic or embryotoxicity. In the rabbit, slight embryotoxicity likely related to maternal toxicity has been reported.
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, Fastum 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, systemic use of prostaglandin synthetase inhibitors including Fastum Gel may induce cardiopulmonary and renal toxicity in the foetus. At the end of the pregnancy, prolonged bleeding time in both the mother and child may occur, and labour can be delayed. Therefore, Fastum is contraindicated during the last trimester of pregnancy (see Section 4.3).

Breast-feeding
No data are available on excretion of ketoprofen in human milk. Ketoprofen is not recommended in nursing mothers.

4.7 Effects on ability to drive and use machines

Not known.

4.8 Undesirable effects

There have been reports of localised skin reactions which might subsequently 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: 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 the intactness of the skin, on the duration of the treatment and on the use of an occlusive bandage (hypersensitivity, gastrointestinal and renal disorders).

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
Immune system disorders				Anaphylactic reactions,including anaphylactic shock, angioedema, hypersensitivity reactions
Gastrointestinal disorders			Peptic ulcer, gastrointestinal bleeding, diarrhoea	
Skin and subcutaneous tissue disorders	Localised skin reactions, such as erythema, pruritus, eczema, burning sensation	Dermatological reactions (photosensitisation, dermatitis bullous, urticaria) Cases of more severe adverse reactions, such as bullous or phlyctenular eczema which may spread beyond the area of application or become generalised.	Dermatitis contact	
Renal and urinary disorders			Newcases or worsening of existing cases of renal insufficiency	

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic category: non-steroid anti-inflammatory drug for topical use. It has anti-inflammatory and analgesic actions.
ATC code: MO2AA10

5.2 Pharmacokinetic properties

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

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

Preclinical safety studies suggest that Fastum Gel is irritant to mucosae and should not be applied to open wounds or lesions of the skin. By single or repeated applications Fastum Gel is well tolerated by the intact skin, although repeated application may locally increase sensitivity to UV light. Fastum Gel has negligible systemic toxicity.

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

i) Five years in aluminium tube
ii) Three years in polypropylene container.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.
Replace the cap after use.
Keep the gel away from naked flames.

6.5 Nature and contents of container

Soft aluminium tube treated inside with non-toxic epoxyresin, containing 30g, 50g, 100g or 2x 50g twin pack or Pump 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 Farmaceutische Riunite S.r.l.
1-3 Via Sette Santi
P.O. Box 412
Florence
Italy

8 MARKETING AUTHORISATION NUMBER

PA0512/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19 August 1992

Date of last renewal: 19 August 2007

10 DATE OF REVISION OF THE TEXT

March 2025