Professional Information for FASTUM GEL

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

FASTUM GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g gel contains 2,5 g ketoprofen.

Excipients with known effects:

Neroli fragrance and lavandin fragrance (containing citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool).

Contains 307 mg ethanol per 1 g.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel.

A mucilaginous, colourless, almost transparent gel with an aromatic flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of localised pain and inflammation associated with acute musculoskeletal injuries.

4.2 Posology and method of administration

Posology

Treatment should not exceed 7 days.

Persons 12 years and older:

Apply to the affected area once or twice daily by gently massaging in order to help absorption.

Apply 5 to 15 cm of gel with each application (100 mg to 300 mg ketoprofen).

Method of administration

Topical.

4.3 Contraindications

- Hypersensitivity or history of hypersensitivity to ketoprofen or to any of the excipients listed in section 6.1.
- History of photosensitivity reactions.
- Known hypersensitivity reactions, such as asthma symptoms, allergic rhinitis and urticaria, to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid or other nonsteroidal anti-inflammatory drugs (NSAIDs).
- History of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate, UV blockers 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).
- Application to pathologically altered skin, such as dermatosis, eczema or acne, around the eyes, to infected skin or to open wounds.
- Third trimester of pregnancy (see section 4.6).
- Safety in children has not been established.

4.4 Special warnings and precautions for use

FASTUM GEL should be used with caution in patients with reduced heart, liver or kidney function.

Isolated cases of systemic adverse reactions affecting the kidneys have been reported.

FASTUM GEL should not be used with occlusive dressings.

FASTUM GEL must not come into contact with the mucous membranes and with the eyes.

The topical use of large quantities of FASTUM GEL can give rise to systemic effects, such as hypersensitivity and asthma.

Topical use of FASTUM GEL, especially if prolonged, can give rise to sensitisation phenomena or local irritation.

Treatment should be interrupted if redness appears.

Treatment should be discontinued immediately upon development of any skin reactions, including cutaneous reactions after co-application of octocrylene-containing products (octocrylene is an excipient used to prevent photodegradation in various cosmetics and personal care products such as shampoos, aftershaves, shower and bath gels, skin creams, lipsticks, anti-ageing creams, make-up removers and hairsprays).

It is recommended to protect treated areas by wearing clothing during treatment with FASTUM GEL and for the two weeks following its discontinuation to avoid the risk of photosensitisation.

Hands should be washed thoroughly after each application of FASTUM GEL.

The recommended treatment length should not be exceeded due to the risk of developing contact dermatitis and of an increase in photosensitivity reactions over time.

Patients with asthma associated with chronic rhinitis, chronic sinusitis and/or nasal polyposis have a higher risk of allergies to aspirin and/or NSAIDs than the rest of the population.

FASTUM GEL is not habit-forming.

The safety and efficacy of FASTUM GEL in children have not been established (see section 4.3)

Elderly patients are particularly susceptible to the adverse effects of nonsteroidal anti-inflammatory drugs (NSAIDs).

Excipient with known effect

FASTUM GEL contains neroli fragrance which in turn contains the allergens citral, citronellols, farnesol, geraniol, d-limonene and linalool, and lavandin fragrance which contains the allergens coumarin, geraniol, d-limonene and linalool. These allergens may cause allergic reactions.

FASTUM GEL contains ethanol that may cause a burning sensation on damaged skin.

4.5 Interaction with other medicines and other forms of interaction

No interactions between FASTUM GEL and other medicines have been observed. Interactions are unlikely as serum concentrations after topical administration are low.

FASTUM GEL should be used with caution in patients who are receiving coumarin anticoagulants. It is advisable to monitor patients receiving coumarin anticoagulants.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety of FASTUM GEL during pregnancy has not been established. Use during the first and second trimester should be avoided.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors, including ketoprofen, may cause cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy, bleeding time may be prolonged in both the mother and the child.

FASTUM GEL is contraindicated during the third trimester of pregnancy (see section 4.3).

Nonsteroidal anti-inflammatory drugs (NSAIDs) can also delay delivery.

Breastfeeding

No data are available on the excretion of ketoprofen, as in FASTUM GEL, in breast milk. After systemic administration, traces of ketoprofen have been found in breast milk. Use of FASTUM GEL is not recommended during lactation.

4.7 Effects on ability to drive and use machines

It is unlikely for FASTUM GEL to affect the ability to drive a vehicle and operate machines.

4.8 Undesirable effects

FASTUM GEL can cause side effects, although not everybody gets them. Undesirable effects of medicines for cutaneous use may occur on the skin. Localised skin reactions have been reported (e.g. erythema, pruritus and burning sensation) which may subsequently spread beyond the area of application and, in some cases, be severe and generalised (e.g. bullous or phlyctenular eczema), in addition to hypersensitivity reactions and skin reactions (photosensitivity). The frequency and extent of these effects are significantly reduced if, during treatment and in the two weeks following treatment, exposure to sunlight, including in a solarium, is avoided.

Other systemic effects of NSAIDs: These depend on the transdermal diffusion of the active ingredient, and thus on the amount of gel applied, the area involved, the degree of skin integrity, the duration of treatment and the use of occlusive dressings (digestive and kidney effects).

The following convention is used to define the frequency of side effects: very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1 000, < 1/100); rare (≥ 1/10 000, < 1/1 000); very rare (< 1/10 000); not known (the frequency cannot be established based on the available data).

Blood and lymphatic system disorders

Very rare: agranulocytosis and thrombocytopenia.

Immune system disorders

Rare: sensitivity reactions.

Not known: anaphylactic reactions, including anaphylactic shock, angioedema, hypersensitivity reactions.

Nervous system disorders

Rare: headache.

Very rare: dizziness, nervousness, depression, insomnia and drowsiness.

Eye disorders

Rare: other ocular reactions.

Very rare: blurred vision

Ear and labyrinth disorders

Very rare: tinnitus.

Gastrointestinal disorders

Rare: peptic ulcer, gastrointestinal bleeding.

Very rare: diarrhoea.

Skin and subcutaneous tissue disorders

Uncommon: localised skin reactions such as erythema, eczema, pruritus and burning sensation.

Rare: dermatological reactions (photosensitisation, bullous eruptions and urticaria). Cases of more severe adverse reactions, such as bullous or phlyctenular eczema which may spread beyond the area of application or become generalised, have occurred rarely.

Very rare: contact dermatitis.

Not known: bullous dermatitis, skin rashes.

Renal and urinary disorders

Very rare: impairment of renal function including interstitial nephritis or nephrotic syndrome, new cases or worsening of existing cases of renal insufficiency.

There have also been reports of isolated cases of systemic adverse reactions such as renal disorders.

General disorders and administration site conditions

Not known: oedema.

Investigations

Very rare: abnormalities of liver function tests.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of FASTUM GEL is important. It allows continued monitoring of the benefit/risk balance of FASTUM GEL. Health care providers are requested to report any suspected adverse drug reactions to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Overdose is unlikely with topical administration. Given the low plasma levels of ketoprofen, as in FASTUM GEL, when applied percutaneously, overdose phenomena can be ruled out. If accidentally ingested, FASTUM GEL may cause systemic undesirable effects depending on the amount ingested. However, if this occurs, treatment will be symptomatic and supportive as in cases of overdose of oral anti-inflammatory medicines.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 3.1 Antirheumatics (anti-inflammatory agents)

Pharmacotherapeutic group: Nonsteroidal anti-inflammatory drugs for topical use.

ATC code: M02AA10

Ketoprofen is a nonsteroidal anti-inflammatory agent. Since ketoprofen is an inhibitor of prostaglandin synthesis, it provides anti-inflammatory, analgesic effects.

FASTUM GEL is ketoprofen in an excipient suitable for allowing it to reach the site of inflammation by transcutaneous route, providing the local treatment of painful joints, tendons, ligaments and muscles.

5.2 Pharmacokinetic properties

After oral administration of a single dose, peak blood concentrations are reached within 2 hours. The plasma half-life of ketoprofen varies from one to 3 hours. Plasma protein binding is 60 – 90 %. Ketoprofen is essentially eliminated through the urine and as glucuronide conjugate; approximately 90 % of the dose administered is excreted within 24 hours.

On the other hand, absorption through the skin is very low. In fact, the percutaneous application of 50 – 150 mg of ketoprofen results in plasma levels of the active ingredient of 0,08 – 0,15 µg/mL approximately 5 – 8 hours after application.

5.3 Preclinical safety data

In animal studies, no embryopathic effects have been found, while there is no epidemiological evidence of the safety of ketoprofen in human pregnancy. Pre-clinical and clinical trials with ketoprofen gel have not shown the appearance of serious adverse events, although anecdotal cases of systemic adverse reactions have been described.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer

Ethanol (96 %)

Neroli fragrance

Lavandin fragrance

Purified water

Triethanolamine.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Tubes

60 months.

Dispensers

36 months.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

Collapsible aluminium tubes of 10 g, 20 g, 30 g, 50 g, 60 g and 100 g.

Cylindrical polypropylene dispensers of 20 g, 50 g, 100 g and 120 g.

Tubes and dispensers are presented in an outer cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Opening of soft aluminium tube

Unscrew the cap and puncture the aluminium membrane with the tip on the outside of the cap.

Priming of dispenser tube

Press the dispenser cap a few times or push the bottom of the tube forwards until gel appears. It is recommended to use the tube in the horizontal position.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Menarini South Africa (Pty) Ltd

Waterside Place, Unit 02D, South Gate Office Park

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8. REGISTRATION NUMBER

Z/3.1/165

9. DATE OF FIRST AUTHORISATION

25 August 1992

10. DATE OF REVISION OF THE TEXT

29 July 2025