# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

Fastum® Gel

## 2. QUALI-QUANTITATIVE COMPOSITION

100 g of gel contain 2.50 g of the active ingredient ketoprofen.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Gel

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Local treatment of rheumatic or traumatic pain in the osteo-articular and muscular systems such as: contusions, distortions, muscle strains, stiff neck, lumbago.

### 4.2 Posology and method of administration

Posology

Apply a thin layer of gel 1 to 3 times daily onto the area of affected skin, gently massaging to help absorption.

Method of administration

*Adults and elderly:*

Tube: Apply a length of gel 5-10cm long (2g) with each application

Dispenser: Apply a length of gel 5-10cm long by pushing the dispenser approximately 3-6 times

*Children under 12 years of age:*

Not recommended as experience in children is limited.

## 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- patients who have a history of hypersensitivity reactions such as asthmatic attacks or other allergic-type reactions to ketoprofen, ASA or other NSAIDs.
- history of any photosensitivity reaction
- known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAID
- history of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate or UV blocker or parfumes
- sun exposure, even in case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation
- The gel should not be used on pathological skin changes such as eczema or acne; or in infectious skin or open wounds.
- 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 consisting of renal affections 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.
- Direct sunlight, including solarium, should be avoided during treatment and for 2 weeks following treatment.
- 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 protect treated areas by wearing clothing during all the application of the product and two weeks following its discontinuation to avoid the risk of photosensitisation.
- The gel must not be used with occlusive dressings.
- 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.

Paediatric population

The safety and efficacy of ketoprofen gel in children have not been established.

## 4.5 Interactions with other medicaments and other forms of interaction

Interactions are unlikely as serum concentrations following topical administration are low. However a close monitoring of patients treated with coumarins is recommended.

## 4.6 Fertility, pregnancy and lactation

Pregnancy

During the first and second trimester:

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.

As the safety of ketoprofen in pregnant women has not been evaluated, the use of ketoprofen during the first and second trimester of pregnancy should be avoided.

During the third trimester of pregnancy:

All prostaglandin synthetase inhibitors including ketoprofen 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. Therefore, ketoprofen is contraindicated during the last trimester of pregnancy.

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 machinery.**

No effects on the ability to drive and use machinery have been reported.

**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 intactness of the skin, on the duration of the treatment and on the use of occlusive bandaging (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 (≥1/1,000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very rare (<1/10,000)
Not known (cannot be estimated from the available data)

| System Organ Class | Uncommon | Rare | Very rare |
|---|---|---|---|
| Immune system disorders | | | Anaphylactic reaction, Hypersensitivity reaction |
| Gastrointestinal disorders | | | Peptic ulcer, Gastrointestinal bleeding, Diarrhoea |
| Skin and subcutaneous tissue disorders | Erythema, Pruritus, Eczema, Burning sensation | Photosensitivity reaction, Dermatitis bullous, Urticaria | Dermatitis contact, Angioedema |
| Renal and urinary disorders | | | Renal failure or insufficiency aggravated |

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

## 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 antiphlogistics.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

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

ATC code: MO2AA10

In a suitable excipient formulation, ketoprofen reaches the site of inflammation by transcutaneous route, allowing local treatment of painful affections of the joints, tendons, ligaments and muscles.

### 5.2 Pharmacokinetic properties

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

By cutaneous route, absorption is instead 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 μg/mL approx. 5-8 hours after application.

### 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.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1. List of excipients

Carbomer, ethanol, neroli fragrance, lavandin fragrance, triethanolamine, purified water.

**6.2. Incompatibilities**

Not applicable.

**6.3. Shelf life**

5 years

**6.4. Special precautions for storage**

Store below 30°C.

**6.5. Nature and contents of container**

Soft aluminium tube coated on the inside with epoxidic, atoxic lacquers.

Tube with dispenser (mechanical pump without propelling gas) consisting of a cylindrical polypropylene container, a polythene piston (pump), a polyacetal valve (on dispensing cap) and a polypropylene closure cap.

**6.6. Special precautions for disposal and other handling**

Opening of soft aluminium tube: unscrew cap and perforate the aluminium diaphragm with the point of the inverted cap.

Pre-filling of the dispensing tube: push the dispenser cap several times or push the base of the tube until the gel appears; it is advisable to use it in a horizontal position.

## 7. MARKETING AUTHORISATION HOLDER

A. Menarini Industrie Farmaceutiche Riunite s.r.l., Via Sette Santi 3, Florence.

## 8. MARKETING AUTHORISATION NUMBER(S)

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

## 10. DATE OF UPDATING OF THE TEXT

July 2018