

## **Package leaflet: Information for the user**

### **Fastum gel 2.5% gel**

Ketoprofen

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

### **What is in this leaflet**

1. What Fastum gel is and what it is used for
2. What you need to know before you use Fastum gel
3. How to use Fastum gel
4. Possible side effects
5. How to store Fastum gel
6. Contents of the pack and further information

#### **1. What Fastum gel is and what it is used for**

Fastum gel contains a medicine called ketoprofen and belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). These reduce inflammation and relieve pain.

Fastum gel is used for the local treatment of rheumatic or traumatic pain in the osteo-articular and muscular system: contusions, distortions, muscle strains, stiff neck, lumbago.

#### **2. What you need to know before you use Fastum gel**

##### **Do not use Fastum gel if:**

- you have a history of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate, UV blockers or perfumes
- you have a history of any photosensitivity reaction
- you are hypersensitive (allergic) to the active substance ketoprofen or any of the other ingredients of fastum gel (see section 6, "Further information" for a list of other ingredients)

- you are hypersensitive (allergic) to, tiaprofenic acid, acetylsalicylic acid, other NSAIDs (e.g. ibuprofen) or any medicines for pain relief or inflammation (allergic symptoms are wheezing (asthma), runny nose (rhinitis) or an itchy rash (hives))
- you are hypersensitive to fenofibrate (a medicine used to lower blood cholesterol)
- Do not expose treated areas to sunlight or UV light from solarium during the treatment and the 2 weeks following 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)

Stop using Fastum gel immediately if you experience any skin reaction including cutaneous reactions after co-application of octocrylene containing products (Octocrylene is one excipient of several cosmetic and hygiene products such as shampoo, after-shave, shower- and bath-gels, skin cream, lipsticks, anti-aging creams, make-up removers, hair sprays in order to delay photodegradation.)

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Fastum gel

- If you have reduced heart, liver or renal function:, talk to your doctor before using Fastum gel: isolated cases of systemic adverse reactions consisting of renal affections have been reported.
- Stop using Fastum gel if rash appears
- Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of octocrylene containing products
- Do not apply Fastum gel to sore, broken or infected skin
- Do not use Fastum gel near the eyes, mouth, nostrils, anal and genital regions
- Do not use with an air-tight or water-tight dressing (i.e. do not bandage, wrap, or cover the area with a plastic dressing)

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

The topical use of large amounts of product may give rise to systemic effects such as hypersensitivity and asthma.

### **Children**

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

### **Protection from the sun and sunbeds**

The exposure to the sun (even hazy) or to UVA of areas in touch with Fastum gel can induce potentially serious cutaneous reactions (photosensitisation). Therefore it is necessary to:

- protect treated areas by wearing clothing during the treatment and for two weeks after its discontinuation to avoid any risk of photosensitisation.
- wash your hands thoroughly after each application of Fastum gel



Do not expose treated areas to sunlight or UV light from solarium during treatment and the 2 weeks following discontinuation.

### **Other medicines and Fastum gel**

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, e.g. oral anticoagulants (blood thinning medicines). This includes medicines you can buy without a prescription. This is because fastum gel can affect the way some other medicines work. Also, some other medicines can affect the way Fastum gel works.

### **Pregnancy and breast-feeding**

Do not use if you are pregnant or breast-feeding. It may affect your baby.

### **Driving and using machines**

Fastum gel should not affect your ability to drive and use machinery.

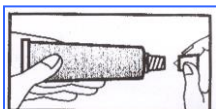
## **3. How to use Fastum gel**

Always use this medicine exactly as described in this leaflet or as your doctor, or pharmacist has told you. Check with your doctor or, pharmacist if you are not sure.

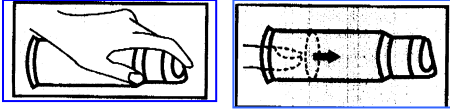
### **The recommended dose is:**

Apply a length of gel 5-10 cm long to the skin of the affected area 1 to 3 times daily.

- tube: unscrew the cap and pierce the aluminium seal with the point in the top of the cap.



- pump dispenser: when using the pump dispenser for the first time, press the top of the dispenser several times or push the bottom until the gel is released. Keep the dispenser in a horizontal position during use (see the pictures below). For 5-10 cm of gel push the dispenser approximately 3-6 times.



### **Use Children under 12 years of age:**

Not recommended as experience in children is limited.

### **How and where to use Fastum gel**

- Fastum gel is for external use only
- Gently massage the gel on the area you need to treat
- Wash your hands immediately after use
- Do not use too much of this medicine.

### **How long should you use Fastum gel for?**

Use Fastum gel only for brief treatment periods.

Consult the doctor if the disorder recurs repeatedly or if you have noted any recent changes in its characteristics.

Do not use Fastum gel for longer than recommended due to the risk of skin reactions (contact dermatitis and photosensitivity).

### **If you use more Fastum gel than you should**

When Fastum gel is externally applied (on the skin) very little reaches the blood. For this reason overdose effects are most unlikely.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

As for other medicaments for topical use, allergy skin reactions may occur. In very rare case Fastum gel can cause severe skin reactions during an exposure of the treated area to the sun light. Localised skin reactions which might subsequently spread beyond the area of application have been reported. 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 depend on the transdermic spreading of the active ingredient and 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).

Stop using Fastum gel and tell your doctor if you notice any of the following side-effects:

**Uncommon side effects** (may affect up to 1 in 100 people) are:

- Erythema
- Pruritus
- Eczema
- Sensation of burning skin

**Rare side effects** (may affect up to 1 in 1,000 people) are:

- Photosensitivity reaction
- Bullous dermatitis
- Urticaria

**Very rare side effects** (may affect less than 1 in 1,000 people) are:

- Contact dermatitis
- Angioedema
- renal failure of aggravated insufficiency
- peptic ulcer
- Gastrointestinal bleeding
- Diarrhoea
- Anaphylactic reaction
- Hypersensitivity reaction

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

Compliance with the instructions inserted in the patient package reduces the risk of undesirable effects.

### **Reporting of suspected adverse reactions**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more

information on the safety of this medicine..

## **5. How to store Fastum gel**

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the carton and tube/dispenser.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Fastum gel contains**

The active substance is ketoprofen.

Fastum gel contains 2.5% ketoprofen.

The other ingredients are carbomer, ethanol, neroli fragrance, lavandin fragrance, triethanolamine, purified water.

### **What Fastum gel looks like and contents of the pack**

Fastum gel is a colourless, almost clear gel.

Fastum gel is available in the following pack sizes: 20 g, 30 g and 50 g collapsible tube or 100 g dispenser.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

*Marketing Authorisation Holder:*

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

*Manufacturer:*

A. Menarini Manufacturing Logistics and Services s.r.l., stabilimento di produzione via Sette Santi, 3 - Firenze.

**This leaflet was last revised in 07/2018.**