

Package leaflet: Information for the user

FASTUM 2.5%GEL

ketoprofen

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet:

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

1. What FASTUM 2.5%GEL is and what it is used for

FASTUM contains ketoprofen and belongs to a group of medicines called anti-inflammatory and antirheumatic drugs (against rheumatism).

FASTUM is used for the local treatment of painful conditions of the osteo-articular and muscular apparatus of rheumatic or traumatic origin: contusions, sprains, muscle strain, torticollis, lower back pain.

You must talk to a doctor if you do not feel better or if you feel worse after 4-5 days.

2. What you need to know before you use FASTUM

a. Do not use FASTUM

- If you are allergic to the active substance or to other related substances, such as fenofibrate, tiaprofenic acid, acetyl salicylic acid or other NSAIDs (non-steroidal anti-inflammatory drugs), or to any of the other ingredients of this medicine (listed in section 6).
- If in the past you have had photosensitisation reactions (skin reactions after exposure to sunlight).
- If in the past you have had allergies to ketoprofen, tiaprofenic acid, fenofibrate, UV sun blockers or perfumes.
- Near open wounds or skin lesions, around the eyes, on skin areas with conditions such as dermatosis, acne or eczema.
- During the third trimester of pregnancy (see section "Pregnancy and breast-feeding").

Do not expose the treated areas to sunlight or the UV lamps of tanning beds during the treatment and in the two weeks after its end.

b. Warnings and precautions

Talk to your doctor or pharmacist before using FASTUM.

The use, especially if prolonged, of products for topical (local) use can give rise to local sensitisation phenomena (increased reactions) or irritation.

Stop using FASTUM immediately if any cutaneous (skin) reactions appear, including reactions after concomitant use of products containing octocrylene (octocrylene is an excipient used to prevent degradation caused by light 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 hair sprays).

The use of large amounts of products for topical use may give rise to systemic effects (that may affect the entire body), such as hypersensitivity (exaggerated sensitivity, such as allergies, towards one or more substances) and asthma.

Exposure of the areas treated with FASTUM to sunlight (even when the sky is hazy) or UV lamps may cause potentially serious skin reactions (photosensitisation). It is therefore necessary:

- **to protect the treated areas from sunlight with suitable clothing for the entire duration of treatment and for the two weeks after its end in order to prevent any risk of photosensitisation;**
- **to wash your hands thoroughly after each application of FASTUM.**

Treatment should be stopped immediately if any skin reactions develop after the application of FASTUM. The treatment should not be administered longer than prescribed: the risk of developing contact dermatitis and photosensitivity reactions increases over time.

Patients with asthma associated with chronic (meaning long-lasting or permanent) rhinitis (inflammation of the nasal mucosa), chronic sinusitis and/or nasal polyps have an increased risk of allergy to aspirin and/or NSAIDs compared to the rest of the population.

Avoid contact with the mucosa and the eyes.

Do not use occlusive bandages (strips of gauze or other materials, as these increase absorption through the skin).

FASTUM is not habit-forming.

Use ketoprofen gel with caution in patients with impaired heart, kidney or liver function: isolated cases of adverse systemic reactions (kidney disorders) have been reported.

c. Children

There are no data supporting the safety and efficacy of ketoprofen gel in children, and its use should therefore be avoided.

d. Other medicines and FASTUM

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

No interactions between FASTUM and other drugs have been observed. However, it is advisable to carry out blood tests in patients in treatment with coumarinic drugs (oral anticoagulants).

e. Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There are no data available regarding any clinical experience with ketoprofen products for topical use during pregnancy; however, based on the data on ketoprofen products for systemic use (forms for oral use or injection):

- Use of ketoprofen during the first and second trimester of pregnancy should be avoided, as its safety has not been evaluated.
- Use of ketoprofen is contraindicated in the third trimester of pregnancy (see "Do not use FASTUM"). NSAIDs can also delay delivery. During the last trimester of pregnancy, the use of NSAIDs, including ketoprofen, may be toxic for the heart, lungs and kidneys of the foetus.
- When ketoprofen is used at the end of pregnancy, bleeding time (the time needed for the blood flow to stop in case of bleeding due to skin cuts) may be prolonged in both the mother and the foetus.

Breast-feeding

After systemic administration, traces of ketoprofen have been found in breast milk. The use of ketoprofen is not recommended in breast-feeding women.

During the first and second trimester of pregnancy and while breast-feeding, FASTUM should only be used after consultation with the doctor and after a joint evaluation of the risk/benefit ratio of the individual case. Talk to your doctor if you think you may be pregnant or are planning to have a baby.

f. Driving and using machines

FASTUM has no influence on the ability to drive and use machines.

3. How to use FASTUM

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

How much

Warning: Do not exceed the recommended doses without your doctor's advice.

Apply a thin layer of gel to the affected skin area.

Do not use occlusive bandages on the area where the medicine has been applied.

In case of allergic or other skin reactions, stop the treatment and talk to your doctor.

When and for how long

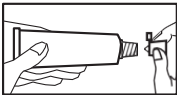
Once or twice a day.

Warning: Only use for short periods of treatment.

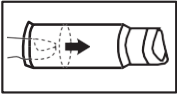
How

Apply the gel and gently rub it in to facilitate absorption. Thoroughly wash your hands after each use.

Tube with screw cap: to open the tube, unscrew the cap and puncture the aluminium membrane with the tip at the top of the cap.



Tube with dispenser: to preload the tube, press the dispenser cap several times or push the tube's bottom forwards until the gel appears; it is recommended to use the tube in a horizontal position.



Talk to your doctor if the problem occurs repeatedly or if you have recently noticed any change in its characteristics.

a. If you use more FASTUM than you should

In case of accidental ingestion of an excessive dose of FASTUM, immediately call your doctor or go to the closest hospital.

Given the low blood levels of FASTUM applied percutaneously (through the skin), phenomena caused by an overdose, that is by the use of an excessive dose of the medicine, can be excluded.

If you have any further questions on the use of this medicine, 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 medicines for cutaneous use, side effects may occur on the skin. Allergic skin reactions and serious skin reactions during exposure to sunlight (photosensitisation) have been reported. In addition, rare cases of more severe adverse reactions have been reported, such as bullous or phlyctenular (presence of fluid-filled blisters) eczema, which may spread beyond the area of application or become generalised. The frequency and extent of these effects are significantly reduced if, during treatment and for the two weeks following treatment, exposure to sunlight, including sun beds, is avoided.

Other systemic side effects of anti-inflammatory drugs depend on the passage of the active substance through the skin 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 bandages (digestive and kidney effects).

Possible side effects are:

a. Uncommon side effects (may affect up to 1 of 100 patients):

- local skin reactions such as erythema, itching, eczema, burning sensation.

b. Rare side effects (may affect up to 1 of 1,000 patients):

- skin reactions, even serious ones, during exposure to sunlight (photosensitisation reactions), bullous eruptions, hives, rare cases of more severe skin reactions such as bullous or phlyctenular (presence of fluid-filled blisters) eczema, which may spread beyond the area of application or become generalised.

c. Very rare side effects (may affect up to 1 of 10,000 patients):

- contact dermatitis (skin inflammation), peptic ulcer, gastrointestinal bleeding, diarrhoea, kidney failure (new cases or worsening of existing cases). Isolated cases of systemic effects (that may affect the entire body) have also been reported, for example kidney disorders.

d. Side effects with unknown frequency (the frequency cannot be estimated from the available data):

- anaphylactic reactions (rapidly developing severe allergic reactions, including anaphylactic shock), angioedema (swelling of the skin and mucosa), hypersensitivity reactions, bullous dermatitis (particular type of skin irritation with the formation of blisters on the skin).

Stop treatment immediately and talk to your doctor if any skin reactions develop after the application of FASTUM.

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

These side effects are generally transitory. However, if they appear it is advisable to talk to your doctor or pharmacist.

Following the instructions in the package leaflet reduces the risk of side effects.

5. How to store FASTUM

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

Do not use this medicine after the expiry date which is stated on the package. The expiry date refers to the last day of that month.

The expiry date stated applies to the product in the unopened, correctly stored package.

It is important to have the information on the medicine available at all times. Keep both the carton and the package leaflet.

Store below 30°C

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

6. Contents of the pack and other information

a. What FASTUM contains

100 g of gel contain:

Active substance: ketoprofen 2.5 g.

Other ingredients: carbomer, ethyl alcohol, neroli fragrance, lavandin fragrance, triethanolamine, purified water.

b. What FASTUM looks like and contents of the pack

FASTUM is intended for use on the skin and is available as a colourless, nearly transparent gel.

Tube with screw cap: tube containing 20 g, 30 g and 50 g of FASTUM 2.5%GEL.

Tube with dispenser: tube containing 20 g, 50 g and 100 g of FASTUM 2.5%GEL.

Not all pack sizes may be marketed.

c. Marketing authorisation holder

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

d. Manufacturer

A. Menarini Manufacturing Logistics and Services S.r.l. production plant via Sette Santi, 3 - Florence.

e. This leaflet was last revised in 10/2019

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are the experts in medicines, their benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed for you.
 - Do not repeat the same prescription without consulting your doctor.
 - Keep all medicaments out of reach of children.
- Council of Arab Health Ministers
Union of Arab Pharmacists