

PACKAGE LEAFLET: INFORMATION FOR THE USER

FASTUM

2.5% gel

KETOPROFEN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

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

1. WHAT FASTUM GEL IS AND WHAT IT IS USED FOR

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

Fastum Gel is used to relieve the pain of soft tissue injuries, and acute strains and sprains. Fastum Gel should only be used by adults and children over 12 years of age.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FASTUM GEL

Do not use Fastum Gel:

- If you are allergic to ketoprofen or to any of the other ingredients of this medicine
- If you are allergic to UV blockers (sun creams) or perfumes
- If you are allergic to aspirin, other NSAIDs (eg ibuprofen) or any medicines for pain relief or inflammation including tiaprofenic acid. Signs of an allergic reaction include wheezing (asthma), runny nose (rhinitis) or an itchy rash (hives)
- If you are allergic to fenofibrate (a medicine used to lower blood cholesterol)

- If you intend to use it on skin conditions such as eczema or acne, an open or infected wound, abscess, ulcer or tumour
- If the area to be treated is near the eyes
- If you are pregnant (see pregnancy and breast-feeding section).

Stop using Fastum Gel immediately

If you experience any skin reaction including reactions after co-application with octocrylene containing products (octocrylene is an ingredient used in several cosmetic and hygiene products such as shampoo, after-shave, shower and bath gels, skin creams, lipsticks, anti-ageing creams, make-up removers and hair sprays in order to delay product breakdown due to sunlight).



Protect your skin from sunlight even on a bright but cloudy day. Do not use sunbeds. This applies during treatment and for two weeks after stopping.

Warnings and precautions

Talk to your doctor before using Fastum Gel:

- If you have heart, liver or kidney problems.
- The use of large amounts of Fastum Gel may give rise to side effects such as hypersensitivity and asthma.
- Exposure to the sun (even hazy) or to UV from a sunbed or solarium of areas treated with Fastum Gel can induce potentially serious skin reactions (photosensitisation). Therefore it is necessary to:
 - Protect treated areas by wearing clothing during treatment and for two weeks following its discontinuation to avoid any risk of photosensitisation.
 - Wash your hands thoroughly after each application of Fastum Gel.
- Treatment should be discontinued immediately upon development of any skin reaction such as rash after application of Fastum Gel.
- Avoid direct sunlight and solarium (sunbeds) during and for 2 weeks after treatment.
- Do not exceed the recommended length of treatment.
- Do not use near mucous membranes (eg lips, vagina).
- If you have asthma as well as a persistent runny nose, sinusitis or nasal polyps, you may have a higher risk of being allergic to aspirin or similar medicines than other people.

Children and adolescents

The safety and efficacy of Fastum Gel in children has not been established.

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).

Fastum Gel with food, drink and alcohol

No known effects

Pregnancy and breast-feeding

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

Driving and using machines

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

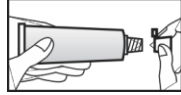
3. HOW TO USE FASTUM GEL

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

How to apply Fastum Gel

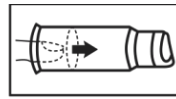
It is important to use Fastum Gel as directed:

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



Apply a length of gel 5-10 cm (2-4 inches) long to the skin of the affected area two or three times daily.

- 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).



Apply 3-6 pushes of the pump dispenser to the skin of the affected area two or three times daily.

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 apply Fastum Gel to sore, broken or infected skin
- Do not use Fastum Gel near the eyes, mouth, nostrils, anal and genital regions
- Stop using Fastum Gel if you get a rash, itchy or sensitive skin after use
- 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)
- Do not use too much of this medicine.

Protection from the sun and sunbeds

- Do not expose the skin that has been treated with Fastum Gel to direct sunlight or sunbeds during treatment or for the following 2 weeks.

Use in children and adolescents

Do not use in children under 12 years of age.

How long should you use Fastum Gel for?

Do not use Fastum Gel for more than 10 days in a row. If your symptoms persist after 10 days, tell your doctor.

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 forget to use Fastum Gel

If you forget a dose, use it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. Do not use a double dose to make up for a forgotten dose.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Fastum Gel can cause side effects, although not everybody gets them.

Stop using Fastum Gel and see your doctor or go to a hospital straight away if you notice any of the following side-effects:

- Localised allergic skin reactions such as redness, swelling, itching and blisters: in some severe cases, these might also spread beyond the area of application (uncommon side effects, may affect up to 1 in 100 people)
- Severe skin reactions (similar to severe sunburn) during exposure to sunlight (rare side effects, may affect up to 1 in 1,000 people)
- Allergic reactions, which may lead to difficulty breathing and/or may be very severe (anaphylaxis). If this occurs, seek medical aid immediately. (not known: frequency cannot be estimated from the available data)
- Cases of more severe forms of eczema which may spread or become generalized have occurred rarely. (rare side effects, may affect up to 1 in 1,000 people)

Tell your doctor or pharmacist if you have any of the following side effects: Uncommon side effects (may affect up to 1 in 100 people) are:

- Sensation of burning skin

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

- Increased sensitivity of your skin to sunlight.
- Skin vesicles (skin blisters)
- Itchy skin reactions (skin rash)

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

- Stomach ulcer, which may be bleeding, and diarrhoea
- Kidney problems (worsening of a pre-existing renal dysfunction)

Not known (cannot be estimated from the available data)

Other effects, which depend on the amount of gel applied, the extent of the area that is treated, skin thickness, length of treatment, and the use of an air-tight or water-tight dressing, are the following:

- A kind of skin infection (known as impetigo)
- Higher than normal levels of eosinophils (a particular kind of blood cell)
- Hypersensitivity (a type of allergic reaction)
- Swelling of the eyelids or of the lips
- Inflammation of blood vessels (known as vasculitis)
- Loose stools
- Interruption of normal functioning of the kidneys
- Higher than normal body temperature
- Complication of wounds

Elderly people are generally more likely to suffer from side effects of Non Steroidal Anti-Inflammatory Drugs (the drug class to which Fastum Gel belongs).

Reporting of side effects

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FASTUM GEL

Keep out of the sight and reach of children.

Store below 25°C.

Do not use Fastum Gel 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 dispose of medicines you no longer use. These measures will help protect the environment.

This leaflet was last revised in 10/2015.