

PACKAGE LEAFLET: INFORMATION FOR THE USER

FASTUM 2.5 %W/W 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 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 other information

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 the active substance ketoprofen or to any of the other ingredients listed in Section 6
- If you have previously had any photosensitivity reactions – an abnormal reaction of the skin to sunlight which may resemble severe sunburn
- If you are hypersensitive (allergic) to UV blockers (sun creams) or perfumes
- If you are allergic to acetylsalicylic acid, other NSAIDs (eg ibuprofen) or any medicines for pain relief or inflammation including tiaprofenic acid
- If you are allergic to fenofibrate (a medicine used to lower blood cholesterol)
- you have had wheezing (asthma), runny nose (rhinitis) or an itchy rash (hives) after taking aspirin or other NSAIDs (eg ibuprofen)
- If you intend to use it on skin conditions such as eczema, acne or infected skin, an open wound or skin lesion (eg abscess, ulcer or tumour)
- If you are in the last 3 months of pregnancy.

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).



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

Warnings and precautions

Talk to your doctor before using Fastum Gel:

- If you have heart, kidney, liver, stomach or bowel problems, or a tendency to bleed easily.
- The duration of treatment should be kept as short as possible as the risk of skin reactions increases over time.
- Exposure to the sun (even hazy) or to UVA 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.
- Do not allow the gel to come into contact with mucous membranes or the eyes.
- Treatment should be discontinued immediately upon development of any skin reaction after application of Fastum Gel.
- If you have asthma, a persistent runny nose, chronic sinusitis and/or nasal polyps, aspirin or similar medicines (such as ketoprofen) may increase the risk of allergy to aspirin, or to similar anti-inflammatory medicines such as ketoprofen which is the active constituent of Fastum Gel.
- Do not cover the treated area with bandages or other occlusive dressings
- Do not use large amounts of Fastum gel as it may give rise to side effects such as hypersensitivity and asthma.

Children and adolescents

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

Talk to your doctor if your symptoms do not improve or if your condition gets worse.

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) or methotrexate (for rheumatoid arthritis, malignant disease or psoriasis).

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 are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not use Fastum Gel if you are in the last 3 months of pregnancy. You should not use Fastum during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. tablets) of ketoprofen can cause adverse effects in your unborn baby. It is not known if the same risk applies to Fastum when it is used on the skin.

Driving and using machines

It has not been established if Fastum Gel could affect your ability to drive and use machinery.

Fastum Gel contains ethanol

This medicine contains 320 mg of alcohol (ethanol 96%) in each g of gel. Ethanol may cause burning sensation on damaged skin.

Fastum Gel contains Neroli fragrance and Lavandin fragrance

This medicine contains fragrances with citral, citronellols, coumarin, farnesol, geraniol, d-limonene and linalool that may cause allergic reactions.

3. How to use Fastum Gel

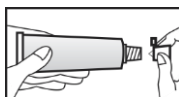
Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose is a length of gel 5-10 cm (2-4 inches) long (3-6 pushes of the pump dispenser) applied to the skin of the affected area two or three times daily.

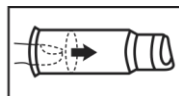
How to apply Fastum Gel

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.



- □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).



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 more than 25g of Fastum Gel per day. The use of large amounts of Fastum Gel may give rise to side effects such as hypersensitivity and asthma.

Protection from the sun and sunbeds

- Do not expose the skin that has been treated with Fastum Gel to direct (even hazy) 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.

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 accidentally ingested, the 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-inflammatories.

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.

Cases of serious reactions such as bullous or phlyctenular eczema (a skin disease with blisters or sores that may extend beyond the area of gel application) or severe skin reactions after exposure of the treated area to sunlight, have been rarely reported.

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:

- Localised allergic skin reactions such as redness, swelling, itching and blisters: in some severe cases, these might also spread beyond the area of application
- Burning sensation

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

- Increased sensitivity of your skin to sunlight.
- Severe skin reactions (similar to severe sunburn) during exposure to sunlight
- Itchy skin rash
- Cases of more severe forms of eczema which may spread or become generalized.

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

- Itchy blistered, dry or cracked skin conditions

Not known (frequency cannot be estimated from the available data)

- A serious allergic reaction, symptoms may include skin rash, swelling of the face, difficulty breathing (anaphylaxis).
- Signs of hypersensitivity/allergy, symptoms may include one or more of the following: hives, itching, swelling, difficulty in breathing.

Other very rare side 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:

- Stomach ulcer, which may be bleeding, and diarrhoea
- Kidney problems (kidney issues may arise or pre-existing kidney problems worsen with use of this product)

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. You can also report side effects directly via the HPRA Pharmacovigilance Website: www.hpra.ie. 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.

This medicinal product does not require any special storage conditions.

Replace the cap after use.

Keep the gel away from naked flames. 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.

6. Contents of the pack and other information

What Fastum Gel contains

The active substance is ketoprofen. 1g gel contains ketoprofen 25 mg.

The other ingredients are: purified water, ethanol, triethanolamine, carbomer, neroli fragrance (containing citral, citronellols, farnesol, geraniol, d-limonene and linalool), lavandin fragrance (containing coumarin, geraniol, d-limonene and linalool).

What Fastum Gel looks like and contents of the pack

Fastum Gel is a colourless or slightly yellowish, almost transparent, with an aromatic odour.. Fastum Gel is available in the following pack sizes - 30 g, 50g, 100g, or 2x50g twinpack tube or in a 50g or 100g pump dispenser.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

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