**Patient Information Leaflet**

**Fastum® 2.5% w/w Gel**  
(ketoprofen)

**Read all of this leaflet carefully before you start using this medicine.**
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**
1. What Fastum gel is and what it is used for
2. Before you use Fastum gel
3. How to use Fastum gel
4. Possible side effects
5. How to store Fastum gel
6. Further information

**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.

**Before you use Fastum gel**
Do not use Fastum Gel and tell your doctor if:
- you have previously had any photosensitivity reactions – an abnormal reaction of the skin to sunlight which may resemble severe sunburn
- you are hypersensitive (allergic) to the active substance ketoprofen, UV blockers (sun creams) or perfumes
- you are hypersensitive (allergic) to any of the other ingredients of Fastum Gel (see Section 6, "Further information" for a list of other ingredients)
- you are hypersensitive (allergic) to aspirin, other NSAIDs (eg ibuprofen) or any medicines for pain relief or inflammation including ibuprofen acid
- you are hypersensitive to fenofibrate (a medicine used to lower blood cholesterol)
- you have had wheezing (asthma), runny nose (rhinitis) or an itchy rash (itchy) after taking aspirin or other NSAIDs (eg ibuprofen)
- 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)
- the area to be treated is near the eyes
- you are pregnant (see pregnancy and breast-feeding section)
- you are breast-feeding

Stop using Fastum Gel immediately if you get a rash, itchy or sore skin reaction. Even if your condition gets worse, do not stop using Fastum Gel without first talking to your doctor or pharmacist.

**How to use Fastum gel**

**How to apply Fastum gel**
It is important to use Fastum Gel as directed:
- unscrew the cap and pierce the aluminium seal with the point in the top of the cap.

**When and how much to use**
Adults and elderly: Apply a length of gel 5-10 cm (2-4 inches) long to the skin of the affected area two to three times daily.
Children under 12 years of age: Not recommended

**How and where to use Fastum gel**

- **If you have heart, kidney, liver, stomach or bowel problems, or a tendency to bleed easily, talk to your doctor before using Fastum Gel.**
- 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 UV 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 other medicines with a similar structure (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.

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.

**Taking other medicines**
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). 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.

**Further information**
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- If you have any further questions, ask your doctor or pharmacist.
- Read all of this leaflet carefully before you start using this medicine.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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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.

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

Possible side effects
Like all medicines, Fastum Gel can cause side effects, although not everybody gets them.
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
- Burring 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
- Blisters on the skin
- 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:
- Signs of hypersensitivity/allergy may include one or more of the following symptoms: hives, itching, swelling, difficulty in breathing
- Inflamed skin causing skin changes resembling eczema may develop as a delayed reaction to sunlight
- Blisters on the lips, eyes or tongue which may swell rapidly causing swallowing or breathing problems. If this occurs, stop taking your medicine and go to a hospital straight away

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 (worsening of a pre-existing kidney problem)
- Allergic reactions, which may lead to difficulty breathing and/or may be very severe (anaphylaxis). If this occurs, seek medical aid immediately.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

How to store Fastum Gel
Keep out of the sight and reach of children.
Do not store above 25°C
Replace the cap after use
Keep the gel away from naked flames
Do not use Fastum Gel after the expiry date which is on the carton and tube after EXP. The expiry date refers to the last day of that month.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Further information
What Fastum Gel contains
The active substance is ketoprofen. Fastum Gel contains 2.5% w/w ketoprofen.
The other ingredients are carbomer 940, ethanol, neroli essence, lavender essence, trolamine and 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 size 100g, tube.
The Parallel Product Authorisation Holder is:
LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.
Repackaged by:
Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.
The manufacturer is:
A. Menarini Manufacturing Logistics and services S.r.l., Via Sette Santi 3, 50131 Florence Italy.
Fastum is a registered trademark of A. Menarini Industrie Farmaceutiche riunite s.r.l.
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Blind or partially sighted?
Is this leaflet hard to see or read?
Phone LTT Pharma Limited, Tel: +44 (0)1527 505414 for help.

Recommendations When Using Fastum Gel
When ketoprofen (contained in Fastum Gel) is applied to the skin, skin reactions (caused photosensitivity reactions) have been reported after the exposure of the treated area to sunlight, even in cloudy weather, and excluding UV from sunlamps.
Therefore the following instructions should be followed before, during the use and for 2 weeks following the discontinuation of Fastum Gel:
- Do not expose treated areas to sunlight (even hazy) including UV from solariun and sunbeds.
- When outdoors, protect treated areas by wearing clothing even in cloudy weather.
- Wash hands thoroughly after each application of the product.
- 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).
- Stop using Fastum Gel immediately if you experience any type of skin reaction and contact your doctor.

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