PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

FASTUM GEL, 2,5 g/100 g

Ketoprofen

Read all of this leaflet carefully because it contains important information for you.

FASTUM GEL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use FASTUM GEL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FASTUM GEL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

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

FASTUM GEL is used for the relief of localised pain and inflammation associated with acute musculoskeletal injuries.

2. What you need to know before you use FASTUM GEL

Do not use FASTUM GEL

- If you are hypersensitive (allergic) or if you have a history of hypersensitivity (allergic) reactions to ketoprofen or any of the other ingredients of FASTUM GEL (listed in section 6).
- If you are hypersensitive (allergic) or if you have a history of hypersensitivity (allergy) to other substances that are chemically related to ketoprofen such as fenofibrate, tiaprofenic acid, acetylsalicylic acid (aspirin) or other nonsteroidal anti-inflammatory drugs (NSAIDs).
- If you have had a photosensitivity reaction (skin reactions after exposure to sunlight) in the past.
- If you have had allergies to UV sun blockers or perfumes in the past.
- Do not expose the treated areas to sunlight or the UV lamps of tanning beds during the treatment with FASTUM GEL and 2 weeks after treatment has been stopped.
- Near open wounds or skin lesions, around the eyes, on skin areas with conditions such as acne or eczema.
- During the third trimester of pregnancy (see Pregnancy and breastfeeding).

Warnings and precautions

Take special care with FASTUM GEL

- FASTUM GEL should not be used with occlusive bandages (strips of gauze or other materials) as these increase the absorption through your skin.
- The use of large amounts of FASTUM GEL topically may give rise to systemic effects (affecting the entire body), such as hypersensitivity (exaggerated sensitivity, such as allergies) and asthma.
- If you use FASTUM GEL for longer periods, you may experience an allergic reaction or irritation; in such cases the treatment with FASTUM GEL should be stopped and a suitable alternate treatment instituted.
- Treatment should be stopped immediately if any skin reactions develop after the application of FASTUM GEL.

- Stop using FASTUM GEL immediately if any 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 hairsprays).
- When using FASTUM GEL avoid exposure of the treated skin area to the sun, both during treatment and for two weeks after treatment because FASTUM GEL has the tendency to make the skin sensitive to sunlight.
- Wash your hands thoroughly after each application of FASTUM GEL.
- Do not apply FASTUM GEL to mucous membranes (the moist linings of the body cavities e.g. inside of the mouth or nasal passages), open wounds or lesions of the skin, or near the eyes.
- The treatment should not be administered longer than prescribed as the risk of developing contact dermatitis (itchy skin rash) and photosensitivity reactions increases over time.
- If you suffer from bleeding disorders, cardiovascular disease, liver or kidney failure, stomach and duodenal ulceration or have a history of such ulceration, use FASTUM GEL with caution.
- If you have asthma associated with chronic rhinitis (meaning long-lasting or permanent inflammation of the nasal mucosa), chronic sinusitis and/or nasal polyps. You have an increased risk of allergy to aspirin and/or NSAIDs compared to the rest of the population.
- FASTUM GEL is not habit-forming.
- If you are an older adult. You may be more prone to the side effects of FASTUM GEL.

Children

The safety and efficacy of FASTUM GEL in children under 12 years of age have not been established.

Other medicines and FASTUM GEL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

No interactions between FASTUM GEL and other medicines have been observed. Interactions are unlikely as serum concentrations after topical administration are low.

FASTUM GEL should be used with caution if you are taking coumarin anticoagulants, medicines that prevent the blood from clotting.

Pregnancy and breastfeeding

Safety of FASTUM GEL during pregnancy and breastfeeding has not been established. FASTUM GEL is contraindicated in the third trimester of pregnancy (see Do not use FASTUM GEL).

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using FASTUM GEL.

Driving and using machines

It is unlikely for FASTUM GEL to affect your ability to drive a vehicle and operate machines.

FASTUM GEL contains neroli fragrance, lavandin fragrance and ethanol

FASTUM GEL contains neroli fragrance which in turn contains the following allergens citral, citronellols, farnesol, geraniol, d-limonene, linalool and lavandin fragrance which in turn contains the following allergens coumarin, geraniol, d-limonene, linalool. These allergens may cause allergic reactions.

FASTUM GEL contains 307 mg ethanol per 1 g. Ethanol may cause a burning sensation on damaged skin.

3. How to use FASTUM GEL

Do not share your medicine with any other person.

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

Treatment should not exceed 7 days.

Persons 12 years and older

Apply to the affected area once or twice daily by gently massaging in order to help absorption.

Apply 5 to 15 cm of gel with each application (100 mg to 300 mg ketoprofen, as in FASTUM GEL).

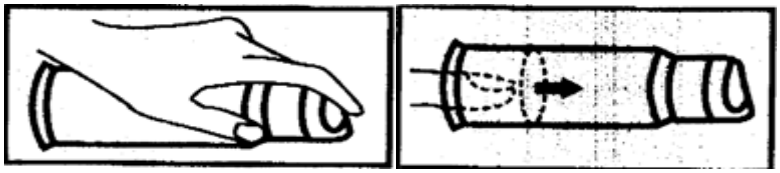
If you have the impression that the effect of FASTUM GEL is too strong or too weak, talk to your doctor or pharmacist.

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 forward until the gel appears. It is recommended to use the tube in a horizontal position.



If you use more FASTUM GEL than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

4. Possible side effects

FASTUM GEL can have side effects. Not all side effects reported for FASTUM GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FASTUM GEL, please consult your health care provider for advice.

If any of the following happens, stop using FASTUM GEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FASTUM GEL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs of recurrent infections such as fever or sore throat.
- Bleeding or bruising more easily than normal.
- Fluid-filled blisters that are widespread and severe.
- Passing less urine than is normal for you.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Headache, dizziness.
- Inability to sleep, drowsiness.
- Nervousness, depression.
- Blurred vision and other ocular reactions.
- Ringing in the ears.
- Ulcer in the stomach or duodenum (symptoms such as pain and discomfort (indigestion) which is felt between the navel and the breastbone).
- Internal bleeding of the stomach and intestines.
- Diarrhoea.
- Skin reactions such as dry, red, itchy, burning sensation.
- Sensitivity of your skin to sunlight.
- Fluid-filled blisters that are localised and mild.
- Abnormalities of liver function tests.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of FASTUM GEL.

5. How to store FASTUM GEL

- Store at or below 25 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date stated on the carton and tube or dispenser.
- Do not dispose of unused medicine in drains or sewerage systems.
- Return all unused medicine to your pharmacist.

6. Contents of the pack and other information

What FASTUM GEL contains

Each 100 g gel contains 2,5 g ketoprofen.

The other ingredients are carbomer, ethanol (96 %), neroli fragrance, lavandin fragrance, purified water and triethanolamine.

What FASTUM GEL looks like and contents of the pack

A mucilaginous, colourless, almost transparent gel with an aromatic flavour.

Collapsible aluminium tubes of 10 g, 20 g, 30 g, 50 g, 60 g and 100 g.

Cylindrical polypropylene dispensers of 20 g, 50 g, 100 g and 120 g.

Tubes and dispensers are presented in an outer cardboard carton.

Not all pack sizes may be marketed.

Holder of certificate of registration

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Access to corresponding Professional Information:

Request via the email address: info@menarini.co.za