FASTUM GEL®

(ketoprofen 2,5%)

COMPOSITION
100g of gel contain:
Active ingredient: ketoprofen 2.50 g
Excipients: carbomer 940, ethyl alcohol, nerol essence, lavender essence, triethanolamine, purified water.

PHARMACEUTICAL FORM AND CONTAINER
FASTUM 2.5% GEL is a gel for external use.
The soft tube and the tube with dispenser contained in the package is of 50 g.

WHAT IS IT?
FASTUM 2.5% GEL belongs to the category of anti-inflammatory and anti-rheumatic drugs.

WHAT IS IT USED FOR?
FASTUM 2.5% GEL is used for the local treatment of rheumatic or traumatic pain in the osteo-articular and muscular system: contusions, distortions, sprains, muscle strains, stiff neck, lumbago.

WHEN SHOULD IT NOT BE USED?
In cases of hypersensitivity to the active ingredient or to any of the excipients or other substances which have a close chemical relation to them, such as acetyl salicylic acid or other non-steroid anti-inflammatory agents and phenofibrate. Ketoprofen gel must not be administered to patients in whom acetyl salicylic acid or other NSAIDs have provoked reactions such as urticaria, rhinitis or asthma.
Ketoprofen gel must not be applied to areas near open wounds or continuous skin lesions, or to the periocular area.

When should it be used only after consulting the doctor?
In patients with hypersensitivity towards the componets of the product (skin allergies) and in patients with serious kidney failure.
The doctor should also be consulted in cases in which the above disorders have occurred in the past.

How to behave during pregnancy and lactation:
The product should not be used during pregnancy and lactation.

WHAT OTHER MEDICAMENTS OR FOODSTUFFS CAN MODIFY THE EFFECT OF THIS MEDICAMENT?
No interactions of FASTUM 2.5% GEL with other drugs have been reported. It is however advisable to carry out blood tests in patients under treatment with cumarinics (oral anti-clotting agents).
If you are using other medicaments, ask your doctor or chemist for advice.

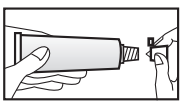
IT IS IMPORTANT TO KNOW THAT
The topical use of the product, especially if it is prolonged, may give rise to phenomena of sensitisation or local irritation.
The topical use of large amounts of the product may give rise to systemic effects such as hypersensitivity or asthma.
To prevent such phenomena of hypersensitivity or photosensitivity, avoid contact with direct sunlight, including the solarium, during treatment and for 2 weeks afterwards.
Interrupt treatment if skin rashes develop. Wash your hands straight after use. Do not use occlusive bandages.
Fastum 2.5% Gel does not cause habituation.
No effects on the ability to drive or to operate machinery have been reported.

HOW TO USE THE MEDICAMENT

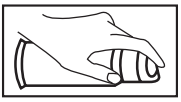
How much
Warning: do not exceed the indicated doses without the doctor's approval.
Apply a thin layer of the gel to the affected skin area.
In the case of allergic or other types of skin reactions, consult the doctor.

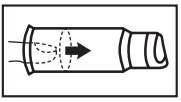
When and for how long
Once or twice daily
Consult the doctor if the disorder recurs repeatedly or if you have noted any recent changes in its characteristics.
Warning: use only for brief treatment periods.

How
Apply the gel and rub gently to help its absorption.
Opening of the soft tube: unscrew the cap and perforate the diaphragm of aluminium with the point of the inverted cap.



Pre-filling of the dispensing tube: push the dispenser cap several times or push the base of the tube until the gel appears; it is advisable to use it in a horizontal position.





WHAT TO DO IF YOU HAVE TAKEN AN EXCESSIVE DOSE OF THE MEDICAMENT
Given the low plasma levels of FASTUM 2.5% GEL applied percutaneously, the possibility of overdose phenomena can be ruled out

UNDESIRABLE EFFECTS
As for other medicaments for topical use, skin reactions may occur. Localised skin reactions have been reported which might subsequently spread beyond the area of application and in isolated cases be severe and generalised.
The frequency and extent of these effects are seen to be considerably reduced if exposure to sunlight, including the solarium, is avoided during treatment and for 2 weeks afterwards.
Other systemic effects of anti-inflammatory drugs depend on the transdermic spreading of the active ingredient and hence on the amount of gel applied, on the surface involved, on the degree of intactness of the skin, on the duration of the treatment and on the use of occlusive bandaging (digestive and renal effects).
Since marketing, the following adverse reactions have been reported. They have been listed according to classes or organ and systems and classified according to their frequency and the following classification: very common (equal to or above 10%); common (ranging between 1% and 10 %), not common (ranging between 0.1% and 1%), rare (ranging between 0.01% and 0.1%); very rare (below 0.01%), including isolated reports.

	Very rare
Gastrointestinal tract alterations	Gastrointestinal disorder
Skin and subcutaneous tissue alterations	Photosensitivity reaction Contact eczema Dermatitis Dermatitis allergic Erythema Urticaria Burns Pruritus Dermatitis bullous
Kidney and urinary tract alterations	Renal disorder

Compliance with the instructions in the patient package insert reduces the risk of undesirable effects.
These undesirable effects are generally transitory. However when they occur it is advisable to consult the doctor or chemist.
It is important to inform the doctor or chemist of the appearance of any undesirable effects not described in the patient package insert.

SHELF-LIFE AND STORAGE
Shelf-life: see the expiry date indicated on the package.
Warning: do not use the medicament after the expiry date indicated on the package.
The indicated expiry date refers to the product whose packaging is intact and which has been correctly stored.
It is important to have the information about the product always available, so keep both the box and the patient package insert.
Storage conditions: store below 25°C
Keep the medicament out of children's reach and sight.

PACKAGE:
Tube of 30gr, 50gr and 100gr of Ketoprofen 2,5%
Dispenser of 50gr and 100gr of Ketoprofen 2,5%
Not all pack sizes may be marketed.

HOLDER OF THE MARKETING AUTHORISATION
A.Menarini Industrie Farmaceutiche Riunite s.r.l. , via Sette Santi 3, Florence, Italy.

DATE OF THE LAST REVISION OF THE TEXT
May 2007

Marketing Authorisation Holder:
A. Menarini Industrie Farmaceutiche Riunite s.r.l. , via Sette Santi 3, Florence, Italy

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