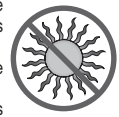
FLEXEN® 2.5% Gel
KETOPROFEN

PHARMACOTHERAPEUTIC CATEGORY - Non-steroidal anti-inflammatory drugs for topical use.
THERAPEUTIC INDICATIONS - Local treatment of: myalgias, muscular tears, bruises, distortions, luxations, bursitis, tendinitis, tenosynovitis, phlebitis and superficial thrombophlebitis, lymphangitis.
CONTRAINDICATIONS - Do not use the product in case of history of previous allergy to ketoprofen, tiaprofenic acid, fenofibrate, UV solar filters or perfumes. Discontinue immediately the use of FLEXEN gel in case of skin reactions including those which develop after the concomitant use of products containing octocrylene (octocrylene is an excipient which is present in various cosmetic products and for the personal hygiene such as shampoo, after shave lotions, gel for shower and bath, skin creams, lipsticks, antiage creams, cleansing products, hair sprays, employed to prevent their photodegradation). Do not expose the treated areas to the sunlight or UV lamps of solarium throughout the treatment and during the two weeks after its discontinuation.



PRECAUTIONS FOR USE - It is advisable to prevent the application of FLEXEN 2.5% gel in correspondence with open wounds or skin lesions.
INTERACTIONS - Inform your doctor or chemist if you have recently taken any other medicinal products also those which are on sale without medical prescription.
No interactions of FLEXEN 2.5% gel with other drugs were found. However, it is appropriate to monitor the patients under treatment with coumarinic agents.
SPECIAL WARNINGS

The exposure to the sunlight (even when the sky is clouded) or to UVA lamps of the areas treated with FLEXEN gel could induce potentially severe skin reactions (photosensitization). Therefore, it is necessary:
- to protect from the sunlight the treated areas with garments throughout the treatment and during the two weeks after its discontinuation in order to prevent any risk of photosensitization
- to wash accurately the hands after each application of FLEXEN gel

Do not use occlusive dressings (strip of gauze or of other material employed which increases the percutaneous absorption). Discontinue immediately the treatment if any skin reaction occurs after the application of FLEXEN gel.
Important information on some excipients - The product contains para-hydroxy-benzoates which could cause allergic reactions, generally of delayed type.
Pregnancy and lactation - For the sake of prudence, unless the physician deems it absolutely necessary, it use during pregnancy is not advised. Consult the physician or chemist before taking any medicinal product.
Effects on the ability to drive and use machines - No effects are known on the ability to drive or use machines.
DOSE, MODE AND TIME OF ADMINISTRATION - Apply onto the skin, one or two times daily, the gel (3-5 cm or more, depending on the size of the involved area), with a gentle massage to favour the drug absorption. Wash the hands accurately and for a long time after each use.
OVERDOSAGE - In case of accidental ingestion/intake of an exceeding dose of FLEXEN 2.5% gel, inform immediately a doctor or go to the nearby hospital.
In view of the low plasma levels of ketoprofen applied by percutaneous route, overdose phenomena can be excluded. If you have some doubts about the use of FLEXEN 2.5% gel, consult your doctor or chemist.
UNDESIRABLE EFFECTS - Like all the medicinal products, FLEXEN gel could cause undesirable effects, thug not all the persons manifest them. Like other medicinal products to be applied on the skin, cutaneous adverse effects could occur. The rate and entity of such effects are remarkably reduced by preventing the exposure to the sunlight, including the solarium, during the treatment and in the two later weeks. The use, especially if long lasting, of products for topical use, could give way to phenomena of sensitization or local irritation. In this instance it is necessary to discontinue the treatment and start-up a suitable therapy
Pathologies of the skin and subcutaneous tissue - Erythema, burning, itching, dermatitis, contact eczema, photosensitivity reactions, urticaria. Skin allergic reactions. Severe skin reactions during the exposure to the sunlight. Rare cases of more severe adverse reactions, such as bullous or phlyctenular eczema, which could extend beyond the application area or become generalized.
Renal and urinary pathologies - Isolated cases of adverse reactions of systemic type, such as renal disorders, were reported.
The compliance with the instructions contained in the product information leaflet reduces the risk of undesired effects.
If any of the undesired effects worsens or if you notice the onset of any undesired effects not listed in this product information leaflet, inform your doctor or chemist.
COMPOSITION - 100 mg contain: Active ingredient: Ketoprofen 2.5 g
Excipients: alcohol (96% ethanol), glycerol, carboxypolymethylene, diethanolamine, methyl-p hydroxybenzoate, propyl p-hydroxybenzoate, depurated water.
PHARMACEUTICAL FORM AND CONTENT - 2.5% gel tube of 50 g for topical use
HOLDER OF THE MARKETING AUTHORISATION
ITALFARMACO S.p.A. – V.le Fulvio Testi 330 – Milano Italy
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