

ketoprofen (cutaneous use)

Core Safety Profile

Formulations: for cutaneous use

4.3 Contraindications

- known hypersensitivity reactions, such as symptoms of asthma, allergic rhinitis to ketoprofen, fenofibrate, tiaprofenic acid, acetylsalicylic acid, or to other NSAID
- history of hypersensitivity to one of the excipients
- history of any photosensitivity reaction
- history of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate or UV blocker or perfumes
- sun exposure, even in case of hazy sun, including UV light from solarium, during the treatment and 2 weeks after its discontinuation
- on pathological skin changes such as eczema or acne; or in infectious skin or open wounds
- third trimester of pregnancy (see section 4.6)

4.4 Special warnings and precautions for use

- The gel should be used with caution in patients with reduced heart, liver or renal function: isolated cases of systemic adverse reactions consisting of renal affections have been reported.
- The gel must not be used with occlusive dressings.
- The gel must not come into contact with mucous membranes or the eyes.
- Treatment should be discontinued immediately upon development of any skin reaction including cutaneous reactions after co-application of octocrylene containing products.
- It is recommended to protect treated areas by wearing clothing during all the application of the product and two weeks following its discontinuation to avoid the risk of photosensitisation.
- Hands should be washed thoroughly after each application of the product.
- The recommended length of treatment should not be exceeded due to the risk of developing contact dermatitis and photosensitivity reactions increases over time.

- Patients with asthma combined with chronic rhinitis, chronic sinusitis, and/or nasal polyposis have a higher risk of allergy to aspirin and/or NSAIDs than the rest of the population.
- The safety and efficacy of ketoprofen gel in children have not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions are unlikely as serum concentrations following cutaneous administration are low.

4.6 Fertility, pregnancy and lactation

In absence of clinical experience with the cutaneous form and by reference with the systemic forms:

Pregnancy

During the first and second trimester:

As the safety of ketoprofen in pregnant women has not been evaluated, the use of ketoprofen during the first and second trimester of pregnancy should be avoided.

During the third trimester:

During the third trimester of pregnancy, all prostaglandin synthetase inhibitors including ketoprofen may induce cardiopulmonary and renal toxicity in the fetus. At the end of the pregnancy, prolonged bleeding time in both mother and child, may occur. Therefore, ketoprofen is contraindicated during the last trimester of pregnancy.

Lactation

No data is available on excretion of ketoprofen in human milk. Ketoprofen is not recommended in nursing mothers.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following CIOMS frequency rating is used: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1000$ to $< 1/100$); rare ($\geq 1/10\ 000$ to $< 1/1000$); very rare ($< 1/10\ 000$), not known (cannot be estimated from the available data).

Immune System disorders

- *Not known*: anaphylactic shock, angioedema, hypersensitivity reactions.

Skin and subcutaneous tissue disorders

- *Uncommon*: Local skin reactions such as erythema, eczema, pruritis, and burning sensations.
- *Rare*: Dermatological: photosensitisation and urticaria. Cases of more severe reactions such as bullous or phlyctenular eczema which may spread or become generalized have occurred rarely.

Renal and urinary disorders

- *Very rare*: Cases of aggravation of previous renal insufficiency.

4.9 Overdose

Overdose is unlikely to be caused by cutaneous administration. If accidentally ingested, the gel may cause systemic adverse effects depending on the amount ingested. However, if they occur, treatment should be symptomatic and supportive in accordance with overdosage of oral antiphlogistics.