

CHECKLIST FOR THE PRESCRIBER

Dear Healthcare professional,

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that photosensitivity reactions (phototoxicity and photoallergy) are important side effects of topical ketoprofen-containing medicines, such as Oruvail, Powergel, Tiloket and Ketoprofen 2.5% Gel.

Several measures are being implemented to ensure the safer use of topical ketoprofen-containing medicines, including that they should only be available under prescription.

The following checklist is provided in order to help you:

- verify that the patient does not have any phototoxicity/photoallergy-related contraindications when prescribing any brand of Ketoprofen 2.5% Gel
- explain to patients the preventive measures they need to take
- check patients' understanding about their risk of photosensitivity and what steps they need to take to minimise this risk.

Contraindications related to phototoxicity and photoallergy of Ketoprofen 2.5% Gel

Before prescribing any brand of Ketoprofen 2.5% Gel, please ensure that the patient satisfies the following conditions:

- No history of photosensitivity reaction
- No history of skin allergy to ketoprofen, tiaprofenic acid, fenofibrate or UV blockers (particularly those containing octocrylene) or perfumes
- Absence of known hypersensitivity reactions, such as symptoms of asthma or allergic rhinitis, to ketoprofen, tiaprofenic acid, acetylsalicylic acid, or to other nonsteroidal anti-inflammatory drugs (NSAID), and fenofibrate.

Preventive risk minimisation measures

In addition, please ensure that patients understand the importance of taking the following precautions to minimise their risk:

- "Do not expose treated areas to sunlight (even cloudy) or UV light from solarium
- "When outdoors, protect treated areas by wearing clothing, during the treatment and for 2 weeks after its discontinuation"
- "Do not use the gel under an occlusive bandage"
- "Wash hands thoroughly after each application of the gel"
- "Do not use any brand of Ketoprofen 2.5% Gel for longer than prescribed".
- "Stop using Ketoprofen 2.5% Gel immediately if any skin reaction develops after using it or after using products containing octocrylene (an ingredient in several cosmetic and hygiene products such as sun blockers, shampoo, after-shave, shower- and bath-gels, skin creams, lipsticks, anti-ageing creams, make-up removers, hair sprays, etc)".