sanofi aventis

Because health matters

Direct Healthcare Professional Communication on risk minimisation measures for ketoprofen-containing topical formulations

Oruvail 2.5% w/w Gel PA 540/119/4 & Orugesic 2.5% w/w Gel PA 540/118/1 (ketoprofen)

9th February 2011

Dear Healthcare Professional

Summary

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) conducted a scientific review of topical ketoprofen-containing medicines on the basis of reported photosensitivity reactions and co-sensitization with octocrylene (UV filter). The CHMP opinion was adopted by the by European Committee decision on 29th November 2010.

The CHMP concluded that photosensitivity reactions with topical ketoprofen-containing medicines are important adverse reactions but that the benefit/risk profile of these medicines remains favourable. Several measures should be implemented for topical ketoprofen-containing medicines to ensure their safer use. In addition these medicines should only be available under prescription.

Recommendations to healthcare professionals

- Prescribers should strictly follow the contraindications when prescribing topical ketoprofen.
- Prescribers and pharmacists should remind patients who are currently taking topical ketoprofen of the importance of using photosensitivity preventive measures such as:
    i. Wash hands thoroughly after each application of the gel.
    ii. Do not expose treated areas to the sun, even if cloudy, or to UVA (including sun-beds) during treatment and following two weeks after discontinuation.
    iii. Protect treated areas from sunlight by wearing clothing.
    iv. Topical ketoprofen should not be used under occlusive bandages.
    v. Discontinue treatment immediately upon development of any skin reaction after application of the product.

Product Discontinuation

Sanofi-aventis have taken the decision to discontinue Orugesic Gel and Oruvail Gel in Ireland. Orugesic Gel has been out of stock since October 2010 and Oruvail Gel will no longer be sold from wholesale level as of 7th February 2011.

Instructions for Pharmacists

Orugesic Gel has always been a prescription-only product and any existing stocks of this product may continue to be dispensed as normal. As of 7th February 2011 no further supply of Oruvail Gel will be available. Packs of Oruvail Gel you currently have in stock may continue to be sold as OTC product until 31st March 2011. After that date the product must be dispensed only in accordance with a

prescription from a registered medical practitioner. Please contact sanofi-aventis at the number below if you have any stock of Oruvail Gel remaining after 31st March 2011.

Further information on the safety concern

Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). In topical formulation, ketoprofen is indicated to treat benign indications in traumatology, as well as in rheumatology. Topical ketoprofen-containing medicines have been available in EU Member States since 1978.

The CHMP recommendations follow a scientific review of reports of cutaneous adverse reactions, including photoallergic reactions, to topical ketoprofen. These reactions include serious reactions leading to hospitalisation. The Committee has however concluded that, on the basis of the available information, the benefits of topical ketoprofen-containing medicines outweigh the risks.

The risk of allergic contact reactions including photoallergy is well established for topical ketoprofen and it has been recognised since the launch of the product that topical ketoprofen may trigger allergic contact reactions including photoallergy. In several Member States this has led to implementation of various measures to ensure safer use of topical ketoprofen such as updates to the product information (SPC/PIL), direct communications to healthcare professionals and the addition of a pictogram on the outer package. The same measures will now be implemented in a harmonised way across EU in all Member States together with a repeated information campaign on correct use of topical ketoprofen. The impact and effectiveness of these measures will be assessed by the CHMP after a three year period.

Following the latest review, the CHMP has recommended that all topical ketoprofen-containing medicines should be available as prescription-only medicines.

Furthermore, the recommendations, outlined above, should be followed for all topical ketoprofen-containing products approved in the EU.

Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions to the Irish Medicines Board **using the on-line reporting function on the IMB website (www.imb.ie) or alternatively by contacting the IMB at 01 6764971.**
In addition, this information may be reported to sanofi-aventis Ireland Ltd., please phone 01-4035600.

Communication information

If you have any further questions or require additional information, please also contact our Medical Information Department 01-4035600 or email IEmedinfo@sanofi-aventis.com

Sincerely,

Dr Velichka Valcheva
Medical Director

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