



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

May 1st, 2012

Fastum Gel PA 512/1/1

Dear Healthcare provider,

Further to the letters sent out on 4th August 2010, 1st December 2010, July 8th, 2011 and December 1st, 2011 this letter is being sent as a reminder about the risk minimisation measures for ketoprofen-containing topical formulations. The content of this letter has been agreed with the Irish Medicines Board.

Summary

In 2010, 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).

CHMP has concluded that photosensitivity reactions of topical ketoprofen-containing medicines are important adverse reactions but that the benefit/risk profile of these medicines remains favourable. Several measures are being implemented in Ireland 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 UVA during the treatment and for two weeks after its discontinuation.
 - iii. Protect treated areas from sunlight by wearing clothing.
 - iv. Topical ketoprofen should not be used under occlusive bandage.
 - v. Discontinue treatment immediately upon development of any skin reaction, including cutaneous reactions after co-application of octocrylene containing products.

Further information on the safety concern

Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). In topical formulations, 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 its risks.

The risk of allergic contact reactions, including photoallergy, is well established for topical ketoprofen and it has been recognised since product launch that ketoprofen gel may trigger allergic contact reactions, including photoallergy. In several Member States this has led to implementation of various risk minimisation measures to support safer use of topical ketoprofen such as updates to the product information (SmPC/PIL), direct communications to healthcare professionals and the addition of a pictogram on the outer package.

As well as in Ireland, the same measures are being implemented in a harmonised way across EU in all Member States together with repeated information campaigns on the correct use of topical ketoprofen. The impact of these measures will be assessed by the CHMP after a three year period following their implementation.

Following this most recent review, 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. The SmPC/PIL for Fastum Gel has been updated accordingly. Please find enclosed a copy of the updated SmPC which is also available on www.medicines.ie.

Call for reporting

Please remember that any suspected adverse reaction following the use of topical ketoprofen-containing medicinal products should be reported to the Irish Medicines Board using the online system at www.imb.ie or alternatively using a freepost yellow card. Reports may also be reported to:

A.Menarini Pharmaceuticals Ireland Ltd.,
Pharmacovigilance Department.
Castlecourt
Monkstown Farm
Monkstown
Glenageary
Co. Dublin

Tel. 01 284 6744
Fax 01 284 6769
Email: ireland@menarini.ie

Communication information:

Should you have any questions or require further information regarding ketoprofen, A.Menarini's Medical Information Department may be reached at 01 284 6744 or 1800 283045.

Patient Educational Pad

Enclosed you will find a pad of patient educational leaflets. We would suggest that a sheet is given to each patient prescribed Fastum Gel as a reminder of the precautions to be taken. Additional pads may be obtained from A.Menarini on 1800 283045.

Sincerely,



Angela Gillian PhD
Medical Manager

Enclosures: SmPC Fastum Gel, June 2011