Direct Healthcare Professional Communication on risk minimization measures for ketoprofen-containing topical formulations such as Fastum ® Gel

Information addressed to general practitioners, surgeons, dermatologists, rheumatologists, physiotherapists and pharmacists.

Dear Healthcare provider,

Summary

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has 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 reaction 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 the UVA during the treatment and the 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 after application of the product.

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 outweighs its risks.

It has been known as soon as 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 repeated information campaign on 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 the latest review, CHMP has recommended that all topical ketoprofen-containing medicines should be available as prescription-only medicines. Further, the recommendations, outlined above, should be followed for all topical ketoprofen-containing products approved in the EU.

The SmPC/PL will be updated accordingly.

Call for reporting

Please remember that any suspect adverse reaction following the use of topical ketoprofen - containing medicinal products should be reported. A. Menarini Industrie Farmaceutiche Riunite s.r.l, Via Sette Santi, 3, Florence Italy, Phone no. +39 055 5680 336, Fax No. +39 055 5680484

Alternatively any suspected adverse reactions can also be reported to:

Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or at: http://www.medicinesauthority.gov.mt/pub/adr.doc

Communication information:

Should you have any questions or require further information regarding Fastum Gel, MAHs Medical Information Department may be reached at A. Menarini Industrie Farmaceutiche Riunite s.r.l, Via Sette Santi, 3, Florence Italy, Phone no. +39 055 5680 336, Fax No. +39 055 5680484.

The content of this letter has been agreed with the European Authorities.

The CHMP's opinion has now been sent to the European Commission for the adoption of a decision.

Sincerely,

Sincerely,

A. Casini

European Qualified Person for Pharmacovigilance,

Menarini

Enclosures:

CHMP press release

Enclosures:

22 July 2010
EMA/CHMP/465633/2010
Press Office

Press release

European Medicines Agency confirms positive benefit-risk balance of topical formulations of ketoprofen

Doctors to inform patients how to use these medicines appropriately

Following a review of topical formulations of ketoprofen, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefit-risk balance of these medicines continues to be positive. However, the Committee recommended that doctors should inform patients on how to use these medicines appropriately to prevent the occurrence of serious skin photosensitivity reactions.

Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). Topical formulations of ketoprofen are used to treat minor trauma, tendonitis, small-joint osteoarthritis, acute low-back pain and phlebitis.

The review of these medicines had been initiated further to concerns over the risk of skin photosensitivity reactions, including photoallergy, and a new risk of co-sensitisation with octocrylene (a chemical sun filter included in several cosmetic and care products).

Having reviewed all available safety data, including data from EU member states' databases and data provided by involved manufacturers, the CHMP concluded that the risk of serious photoallergic reactions was very low (1 case per 1 million patients treated) and that this risk could be minimised by harmonised risk-minimisation measures.

The Committee recommended that topical ketoprofen should only be used when prescribed by a physician. The CHMP also recommended strengthening the contra-indications and warnings on sun exposure and a warning on the risk of co-sensitisation when used together with octocrylene-containing products.

The CHMP's recommendation has been forwarded to the European Commission for the adoption of a binding decision.

Notes

1. More information on this review is available in the document: Questions and answers on the review of the marketing authorisations for topical formulations of ketoprofen.

2. Topical ketoprofen-containing medicines (creams, gels, solutions and plasters) have been available in all Member States except for the Netherlands since 1978.

3. The review of Ketoprofen was conducted in the context of a formal review, initiated by France under Article 107 of Directive 2001/83/EC, as amended.

4. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu.

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