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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.

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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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