

Malta, 26th July 2010
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Dear Healthcare Professional

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

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, 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.

In Malta, topical Ketoprofen is found in Profenid® Gel, Ketoprofen 2.5%® Gel, Fastum® Gel Artrosilene 5% Gel and Artrosilene 15% Cutfoam.

The Medicines Authority has participated in these discussions held at the EMA and is in agreement with the full [press release](#) issued by the EMA, attached here for your perusal. More information on this review is available in a separate [questions-and-answers](#) document

Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.