

PRESS RELEASE

Helsinn Healthcare SA, nimesulide is a safe drug

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With reference to the Irish Medicine Board (IMB) decision, mainly based on 6 cases of hepatic damage, to suspend the marketing and sale of nimesulide and following the request to the European Committee for Medicinal Products for Human Use (CHMP) to revise the benefit/risk profile of the drug, Helsinn Healthcare deems opportune to specify that nimesulide is a drug with a positive safety profile as demonstrated by the 500 million patients to whom it has been administered in the last 22 years.

The alleged correlation between the use of nimesulide and the 6 cases of hepatic damage occurred between 1999 and 2006, as reported by the National Liver Transplant Unit at St. Vincent's University Hospital (Ireland), is still under evaluation.

Liver damage is a rare adverse effect that is already known with regards to the entire non-steroidal anti-inflammatory drugs therapeutic class (NSAIDs), as indicated in the Summary of Product Characteristics (SPC).

In a recent and independent study (G. Traversa, C. Bianchi, R. Da Cas, I. Abraha, F. Menniti-Ippolito and M. Venegoni) performed on behalf of the Italian National Health Service Scientific Body (Istituto Superiore di Sanità –ISS) and published by the British Medical Journal, the risk of liver damage correlated to NSAIDs administration was classified as extremely rare, and was specifically observed that there were no differences between the use of nimesulide and other drugs of the same therapeutic class.

In 2003 nimesulide has already been under revision by the EMEA which confirmed the positive benefit/risk ratio in correct usage conditions and in accordance to the prescribing information and indications: it is here underlined that the drug can be administered only if prescribed by a physician.

Helsinn Healthcare is working to ensure that a full comprehensive review of all safety data is completed as soon as possible.

In the meanwhile, it is worth highlighting that the prescription and use in compliance with the approved SPC are fundamental to guarantee that nimesulide continues to stand as an effective and safe therapeutic choice for the treatment of various conditions characterized by acute pain.