

QSM/MC/IEA.113

23 May 2007

Information Exchange System

Alert No. 113

Oral nimesulide: marketing suspended in Ireland due to reports of liver failure

The Irish Medicines Board (IMB) has announced the suspension of the marketing and sale of nimesulide-containing medicinal products for oral use available in Ireland, with immediate effect. The suspended products include Aulin (100 mg tablets and granules), Mesulid (100 mg tablets and granules) and Mesine (100 mg tablets). The IMB decision was based on new information from a National Liver transplant Unit that six patients required liver transplant following treatment with nimesulide.

Nimesulide is a non-steroidal anti-inflammatory medicine authorized in many countries for the treatment of acute pain, the symptomatic treatment of painful osteoarthritis and for primary dysmenorrhoea. Liver damage is a serious and rare damage known to occur with nimesulide and the IMB had previously issued advice to health-care professionals regarding this risk. The IMB has received 53-liver related adverse reaction reports with nimesulide since the product was first approved for use in Ireland in 1995.

The IMB has notified the medicines regulatory authorities throughout Europe of the six new cases of nimesulide associated liver failure and has initiated a referral for a full safety review of nimesulide-containing products by the European Medicines Agency (EMA).

This Alert is being issued for wider dissemination of the IMB decision to suspend oral nimesulide-containing products from the Irish market.

In the WHO database there are a total number of 320 reports of liver and biliary system disorders in patients who received nimesulide. Of these, 18 cases have been shown to have a clear association with nimesulide use.

Reference:

Press Release from the Irish Medicines Board, 15 May 2007.