

15th May 2007

IMB ANNOUNCES IMMEDIATE SUSPENSION OF THE MARKETING OF MEDICINES CONTAINING NIMESULIDE

The Irish Medicines Board [IMB] today announced the suspension of the marketing and sale of nimesulide-containing medicinal products for oral use available in Ireland, with immediate effect.

The products concerned are:

Product Name	Marketing Authorisation Number
Aulin 100mg Tablets	PA 294/18/1
Aulin 100mg Granules	PA 294/18/2
Mesulid 100mg Granules	PA 915/1/1
Mesulid 100mg Tablets	PA 915/1/2
Mesine 100mg Tablets	PA 281/111/1
Aulin 100mg Tablets	PPA 465/110/1
Aulin 100mg Granules	PPA 1328/51/1
Aulin 100mg Tablets	PPA 1328/51/2

Nimesulide is a non-steroidal anti-inflammatory medicine that is authorised in Ireland since 1995 for the treatment of acute pain, the symptomatic treatment of painful osteoarthritis and for primary dysmenorrhoea [period pains]. It is available only on prescription.

Liver damage is a rare but serious adverse effect known to occur with nimesulide and the IMB has previously issued advice to healthcare professionals regarding this risk. The IMB has now been provided with information from the National Liver Transplant Unit at St. Vincent's University Hospital on six patients who required liver transplant following treatment with nimesulide. Since nimesulide was first licensed in Ireland in 1995, a total of 53 liver-related adverse reaction reports have been received. This includes 9 cases of liver failure, 6 of which originated from the National Liver Transplant Unit. Three cases of liver failure resulted in a fatal outcome and the IMB is aware of one additional liver-related fatality.

The IMB has notified the medicines regulatory authorities throughout Europe and has initiated a review of the safety of nimesulide-containing products.

Advice to patients/consumers:

1. Stop taking the medicine immediately.
2. Return to your doctor for a review of your condition and further advice.
3. Return any remaining packs (unused or partially used) of the above products to your pharmacist.

The IMB is working to inform all patients, doctors, and pharmacists of this issue and has instructed the relevant companies to recall their products from all patients / consumers, pharmacies, hospitals and wholesalers immediately.

Further information, including a Questions and Answers document, is available on the IMB website at www.imb.ie.

Patients and healthcare professionals who have any queries can contact the IMB on the following helpline numbers: Freephone 1-800-251054 or 01-6343555.

ENDS

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