

**Notice Information: Human Medicines - Recall
15 May 2007**

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Active Substance:
- d) Serial/Batch Number & Expiry Date:
- e) Authorisation Holder:
- f) Prescription Required:

Part 2. Target Audience

- a) Target Audience:

Part 3. Problem/Issue

a) Problem/Issue:

Immediate Recall of Nimesulide Containing Oral Products The Irish Medicines Board (IMB) wishes to advise you that all batches of the above-mentioned Aulin, Mesulid and Mesine medicinal products are being recalled with immediate effect. Please note that Aulin 3% w/w Gel (PA 294/18/3) and Mesulid 3% w/w Gel (PA 915/1/3) are not included in this recall. The recall is going to patient level, and follows the suspension by the IMB of the marketing authorisations listed above. The respective Marketing Authorisation Holders are assisting with this recall. Notification of the patient level recall is via a press statement which has been issued by the IMB to the general public. A formal notification has also been placed in national newspapers. The reason for the suspension and recall is that new safety information has become available concerning hepatic-related adverse reaction reports associated with nimesulide-containing products. 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.

Part 4. Action to be taken

a) Action to be taken:

Patients are immediately requested to do the following: 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 (both unopened and partially used) to your Pharmacist immediately. Healthcare Professionals are immediately requested to do the following: 1. Quarantine any packs (including free medical samples) of these products which you have in your possession 2. Await the uplift of these packs by the companies concerned. . Specific Information for Pharmacists : Pharmacists are immediately requested to do the following: Please identify and quarantine all units of the above-mentioned Aulin, Mesulid or Mesine medicinal products which are located within your hospital or retail pharmacy. Please note that this includes both unopened and partially used packs. For Hospital Pharmacists Only : In addition to stock of the above-mentioned Aulin, Mesulid or Mesine medicinal products which are located within your pharmacy, please also identify and quarantine all units which are on wards. Please contact the following company representatives who will arrange for direct uplift of any units of their product(s) which you have: • Helsinn Birex Pharmaceuticals Ltd, Helsinn Birex Therapeutics Ltd & Ergha Healthcare – Mr. Tom Henderson, Tel. 01-8030016 • Pinewood Laboratories Ltd - Ms. Ann Melvin, 01-4569123, LoCall 1850 207 207 • PCO Manufacturing Ltd – Mr. Derek Colman, 01-4507090 Please note that since this recall is going to patient level, patients will be returning stock (both unopened and partially used) to their pharmacy. Please receive this stock back from patients and place in quarantine for uplifting. An IMB press statement, issued on May 15th, 2007 has advised patients to return to their doctor for a review of their condition and for further advice. Please report any suspected adverse reactions which you may become aware of to the respective Marketing Authorisation Holder or the IMB in the usual way. Wholesalers are immediately requested to do the following : Please immediately quarantine any units of the above mentioned products which you have in your possession. Please contact the following company representatives to arrange for the return of these units from your premises. • Helsinn Birex Pharmaceuticals Ltd, Helsinn Birex Therapeutics Ltd & Ergha Healthcare – Mr. Tom Henderson, Tel. 01-8030016 • Pinewood Laboratories Ltd - Ms. Linda Kennedy, 01-4569123 • PCO Manufacturing Ltd – Mr. Derek Colman, 01-4507090 Should you have any queries regarding this recall, please contact the following company representatives: • Helsinn Birex Pharmaceuticals Ltd, Helsinn Birex Therapeutics Ltd & Ergha Healthcare – Mr. Tom Henderson, Tel. 01-8030016 • Pinewood Laboratories Ltd – Ms. Ann Melvin, 01-4569123, LoCall 1850 207 207 • PCO Manufacturing Ltd - Mr. Frank Brownen, 01-4507090 Further information on this issue, including a Questions and Answers document can be viewed here. If you have any queries, the IMB may be contacted on the following helpline numbers: Freephone 1-800-251054 or 01-6343555.

Part 5. Enquiries

- a) All enquiries should be made to:

If you have any queries, the IMB may be contacted on the following helpline numbers: Freephone 1-800-251054 or 01-6343555.

Part 6. Keywords

- a) Keywords:

nimesulide nsaid