

Notice Information: Human Medicines - Recall

18 October 2006

Part 1. Product Information

- a) Title: Extended Recall of Paratabs 500mg Tablets
- b) Product Name/Type: PARATABS 500MG TABLETS
- c) Active Substance: paracetamol
- d) Serial/Batch Number & Expiry Date: All batches - all dates.
- e) Authorisation Number: PA 281/74/1
- f) Manufacturer/Supplier: Pinewood Laboratories Ltd., trading as Pinewood Healthcare

Part 2. Problem/Issue

- a) Problem/Issue: The Irish Medicines Board (IMB) is today issuing an urgent notice for patients in Ireland who have been dispensed any batch of Paratabs 500mg Tablets (paracetamol). This recall action is an extension of the recall of Paratabs Tablets, batch number 6022, which occurred on September 27th, 2006. This notice follows the precautionary recall of all remaining batches of Paratabs 500mg Tablets by its marketing authorisation [MA] holder, Pinewood Laboratories Ltd., (trading as Pinewood Healthcare), due to contamination of several additional batches to that identified in September. The cause of this contamination is being investigated, but it is likely to be a mould. Paratabs 500mg Tablets could not have been bought over the counter in grocery stores or over the counter in pharmacies. They would only have been dispensed by your pharmacist on foot of a prescription from your doctor. *Note: Blister packs of Paratabs or of other paracetamol products are not affected*.

Part 3. Action to be taken

a) Action to be taken:

Patients: The IMB is requesting all patients who have been dispensed Paratabs 500mg Tablets to do the following as soon as possible: 1. Check the label of the paracetamol tablets that have been dispensed to you to determine if they are Paratabs 500mg Tablets. 2. If they are Paratabs 500mg Tablets, or, if you are unsure about them, you should not take any more of the tablets, and you should return them immediately to your pharmacist. 3. You should tell your pharmacist that you are returning your medicine because of this issue. 4. The pharmacist will be able to dispense alternative paracetamol tablets. Pharmacists: Pharmacists will receive a recall letter from Pinewood Laboratories Ltd., over the coming days. In the meantime, pharmacists should quarantine any unsold packs (including partial packs) of Paratabs 500mg Tablets in 100 Tablet Dispensing Packs and await the instruction in the recall letter. Patients are being requested to returning any unused packs (including partial packs) to their pharmacy. The IMB is working with Pinewood Laboratories Ltd. to recall all batches of Paratabs 500mg Tablets from patients, pharmacies, hospitals and wholesalers, and to inform all physicians, pharmacists and patients of this issue. The IMB is also continuing to investigate the cause of the contamination with Pinewood Laboratories Ltd.

Part 4. Enquiries

a) All enquiries should be made to:

FOR INFORMATION: Siobhan Molloy/Avril Collins Weber Shandwick
FCC Tel: (01) 676 01 68 or (086) 817 50 66 / (086) 396 4368

Part 5. Keywords

a) Keywords:

paratabs paracetamol