DRUG SAFETY NEWSLETTER

NOTIFICATION OF CHANGES IN AVAILABILITY OF OTC MEDICINES

IRISH MEDICINES BOARD

PARACETAMOL

You may be aware that, some time ago, the Minister for Health, requested the National Drugs Advisory Board to undertake a review of the control of sale and supply of paracetamol-containing products in Ireland. While paracetamol is acknowledged as an effective and safe medicine when used properly, the consequences of overdose are potentially very serious with the risk of irreversible liver damage. As a result, it was considered prudent to review its availability and the resulting recommendations were approved by the Minister. The following are revised conditions which will apply to the sale of paracetamol:

1. Warnings

(a) The statement **"CONTAINS PARACETAMOL"** should be clearly carried in contrasting boxed bold type on the package together with the following warning: **"DO NOT TAKE ANY OTHER PARACETAMOL CONTAINING PRODUCTS".**

(b)The package label should also contain the following precaution **"IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE EVEN IF YOU FEEL WELL. PLEASE READ THE ENCLOSED LEAFLET CAREFULLY".** The package leaflet should contain the following statement, **"IMMEDIATE MEDICAL ADVICE SHOULD BE SOUGHT IN THE EVENT OF OVERDOSAGE, BECAUSE OF THE RISK OF IRREVERSIBLE LIVER DAMAGE".** If the package does not contain a leaflet, then the latter statement should replace the former on the package label.

2. Packaging

All over-the-counter paracetamol tablets should be packaged in blister packs or in comparable individually wrapped, child resistant, dosage units.

3. Pharmacy Sales

The maximum pack size of paracetamol-containing products for over-the-counter sale in pharmacy outlets will be restricted to a total of 24 x 500mg tablets or the equivalent amount of paracetamol and 140ml of paracetamol paediatric (120mg/5ml) or junior formulations (250mg/5ml) or the equivalent. Supply of more than one pack to an individual patient should be supervised by and at the discretion of the pharmacist. Supply of more than 50 tablets should be on the basis of a prescription. This does not affect dispensing packs.

4. Non-Pharmacy Sales

Emergency supplies of paracetamol as single ingredient preparations will only be available in non-pharmacy outlets with the following restriction:

The maximum pack size will be restricted to a total of 12 x 500mg tablets or the equivalent amount of paracetamol, packaged in single unit dose packs for adult use and 60ml (120mg/5ml) for liquid paediatric formulations. Only one pack should be supplied on each occasion of purchase.

5. Implementation

These new requirements will come into effect immediately for all new paracetamol-containing preparations. The latest date for implementation of these requirements for existing paracetamol-containing products is 30th September 1997.

TERFENADINE

Terfenadine is an antihistamine agent that has been authorised in Ireland for over 15 years, and has been available as an over-the-counter medicine since 1987. It has a good safety record when used as recommended but in certain circumstances it may cause arrhythmias. This association with cardiovascular events, especially when used in combination with other specific drugs is well known. Special warnings relating to these possible interactions are detailed in the patient leaflet. The Board has kept this matter under constant review and in recent years has notified healthcare professionals of this potential problem by way of a "Dear Doctor/Pharmacist" letter.

To date, the Board has received only isolated reports of such problems associated with usage of terfenadine in Ireland and there have been no deaths.

The Board, in association with the EU Committee for Proprietary Medicinal Products, has recently undertaken an extensive review of terfenadine and other similar anti-histamine agents, and a formal legally binding opinion will be issued by the EU Commission shortly.

In addition, in recent months the Board and its experts have been actively reviewing the availability of terfenadine as an over-the-counter medicine. This review involved evaluation of data, from both national and international sources as well as detailed information submitted by the company.

This review has shown that serious adverse reactions continue to be reported despite identification of the risk factors. Because it appears that many of the reported cases could have been avoided, the Board has considered it necessary to recommend that terfenadine should only be used under medical supervision and therefore has decided to change its status to a prescription only medicine. This decision was reached because of the increasing complexity of the precautions needed to ensure safe use of terfenadine. This change will come into effect immediately.

The company is co-operating full with the Board and will be in touch with doctors and pharmacists in the very near future regarding the change in status of terfenadine.

You are reminded of the following precautions/warnings relating to use of Terfenadine:

- **Terfenadine should not be used by patients with cardiac or hepatic disease.**
- **The recommended dosage must not be exceeded (i.e. 120mg/day for adults).**
- **Terfenadine should not be taken with grapefruit juice.**
- **The following drugs have been reported to cause interactions:-**
  Ketoconazole, Itraconazole and related imidazole anti-fungal agents,
  Erythromycin, Clarithromycin and related macrolide antibiotics.

You are requested to report any suspected adverse reactions to the Board.

Currently marketed OTC terfenadine products:
Triludan and Triludan Forte

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