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Newsletter Number 17

14th June 2001

INFORMATION CIRCULAR FOR PHARMACISTS IN TASMANIA

1. Changes to the Tasmanian Poisons List

Consistent with the recommendations of the National Drugs and Poisons Scheduling Committee a number of amendments have been made to the Tasmanian Poisons List which take effect from the 1st June 2001. Below are detailed the more notable changes.

1.1. Schedule 2- New entries

FAMOTIDINE for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

RANITIDINE for the relief of symptoms of gastro-oesophageal reflux, in packs containing not more than 14 days supply.

***Background:** The committee considered a submission for the transfer of these agents to Schedule 2. The move was supported because of well established safety data and indications meeting Schedule 2 criteria. Mandatory pack warnings advise that these products are only for short-term use and that medical advice should be sought for recurrence of symptoms. Scheduling is consistent with availability in the U.S., U.K., Canada and N.Z.*

1.2 Schedule 2 Amendments

*GLYCERYL TRINITRATE **except** when included in Schedule 3 or 4.
(*Nitrate scheduling is clarified below)

1.3 Schedule 3- New Entries

FLUTICASONE (Flixonase?) in aqueous nasal sprays delivering 50 micrograms or less of fluticasone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 200 actuations or less, for the short-term prophylaxis or treatment of seasonal allergic rhinitis in adults and children 12 years and over.

*GLYCERYL TRINITRATE in oral preparations.

*ISOSORBIDE DINITRATE in oral preparations containing 10mg or less of isosorbide dinitrate per dosage unit.

1.4 Schedule 3- Amendments

AMINOPHYLLINE in liquid oral preparations containing 2 per cent or less of aminophylline.

THEOPHYLLINE in liquid oral preparations containing 2 per cent or less of theophylline.

Background: *This amendment has put a ceiling on the strength of xanthine products in Schedule 3. This was the result of a public health and safety review of the toxicity of this class. Whilst the committee concluded that there is not the evidence of harm with the liquid products in Schedule 3 there is a recognised toxicity with the xanthines and that there has been a declining use of this group of drugs in respiratory disease management. There is no change to the scheduling of Brondecon? or Nuelin? syrups*

1.5 Schedule 4- Amendments

VITAMIN A for human therapeutic or cosmetic use is included in Schedule 4. The Poisons List then provides for exceptions. In summary these exceptions are:

- I. topical preparations containing 1% or less of vitamin A
- II. internal preparations containing 100 IU or less per dosage unit
- III. other internal preparations with a recommended daily dose of 5,000 IU or less of vitamin A where a product is labelled with the following statements:
 - (a) The recommended adult daily amount of vitamin A from all sources is 2,500 IU
 - (b) **WARNING-** When taken in excess of 8,000 IU vitamin A can cause birth defects. If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The new warning statement (b) is to be phased in over 1 year and has been much debated with submissions from industry and interested groups. The level at which vitamin A is a teratogen is contentious and is complicated by the fact that the Australian diet includes sources rich in pre-formed vitamin A such as sheep liver. **When advising a patient a pharmacist should consider that there may be significant intake of this vitamin from both the supplement and dietary sources.**

The NDPSC was of the opinion that the epidemiological data supported the conclusion that a total daily intake of vitamin A of 8,000 IU or less is not associated with birth defects. The limit advised by the committee was supported by the conclusion of the European Teratology Society in 1999 that: "Currently there is insufficient human evidence to derive a threshold daily intake above which there may be teratogenic effects, but the evidence is reassuring with respect to the lack of detectable teratogenic effects at or below the maximum amount of 8-11,000 IU which it is recommended pregnant women should not exceed".

2. Nitrate Scheduling Summary

The scheduling of the nitrates has been subject to full review. Changes in scheduling have been incorporated in the Tasmanian Poisons List in two separate amendments. In summary from the 1st June nitrate preparations are subject to the following scheduling:

Schedule 4- Nitrates for ischaemia prophylaxis

Transdermal glyceryl trinitrate patches, isosorbide mononitrate (e.g. Monodur ?), Nitrobid ointment? . Also includes glyceryl trinitrate for injection.

Schedule 3- Preparations for acute treatment

Glyceryl trinitrate in oral preparations (Anginine, Nitrolingual spray?), isosorbide dinitrate 10mg or less is in Schedule 3 (Isordil ?).

Schedule 2- Glyceryl trinitrate for anorectal use (Rectogesic ?)

3. **For information: Scheduling of Citrus Oils (Bergamot, lemon, lime and bitter orange oils) in Schedule 5**

A sub-committee of the NDPSC has been reviewing the toxicity of a large group of essential oils over the last 5 years. In this process the sub -committee identified the photo -

sensitising hazard of citrus oils when applied to the skin. This hazard is due to the furanocoumarin component of these oils. Furanocoumarins are destroyed by steam distillation or the hazard is lessened at low concentration or by the washing of the product from the skin (i.e. with soaps, bath or shower gels) and accordingly exemptions are provided where the risk is ameliorated. Exemption from scheduling is also provided where the label carries the statement "Application to skin may increase sensitivity to sunlight".

4. Sedating Antihistamines and Children

The provision of sedating antihistamines for use in children has recently been raised in the general press. This issue has been covered in the May 1999 newsletter which advised as follows" All states and territories now rely on the professional discretion of pharmacists not to supply sedating antihistamines for the sedation of children. In particular the Commonwealth Medicines Evaluation Committee (MEC) advise that the treatment of children of less than two years of age with antihistamines be only undertaken following medical advice and that promethazine in particular should *not* be used for children less than 12 months of age. The use of antihistamines in children between 2 years of age and 11 years is on the advice of a doctor or pharmacist."

5. Narcotic Registers

Please note that compliance with Poisons Regulation 12 mandates the use of narcotic registers approved by the Secretary of the Department. Pharmacists have commented on the cost of registers and use issues; however loose leaf pages are not compliant with the law. There are currently two registers approved for use in pharmacies:

1. The Narcotic Substances Register - 1978 Edition (Red cover)
Available from the Printing Authority of Tasmania, Faulding and Sigma.
2. The Drug of Addiction Register (Code: VHA REG 10)
A Victorian publication which is available from Hospital Supplies of Australia (Approx. cost \$16) and through Sigma.

6. List of Schedule 3 Recordable Drugs (S3R)

The following substances when in Schedule 3 are required to be recorded (Reg.34B) :

Aminophylline
Dihydrocodeine in undivided preparations
Salbutamol
Terbutaline
Theophylline

5. New Codes

519	MS Mono Capsules 30mg
520	MS Mono Capsules 60mg
521	MS Mono Capsules 90mg
522	MS Mono Capsules 120mg
523	MS Contin tablet 15mg
524	Oxynorm Capsules 5mg

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