

Newsletter Number 13

9th June 2000

Information Circular for Pharmacists in Tasmania

Changes to the Tasmanian Poisons List Effective Date- 1st July 2000

Consistent with the recommendations of the National Drugs and Poisons Scheduling Committee (N.D.P.S.C.) the following changes come into effect 1st July 2000. Please note that this is a summary of the more notable changes and is not a full list. A copy of the Poisons List and the Poisons Act may be accessed via the internet site www.thelaw.tas.gov.au/. The Poisons Regulations are not available at this site but can be obtained by contacting 6233 2064 and an unofficial office copy can be provided by e-mail. Hard copies of all legislation are available from the Printing Authority of Tasmania (Tel: 6233 3289).

Schedule 2

Amendments

Benzoyl peroxide in preparations for human therapeutic use containing 10% or less of benzoyl peroxide **except** in preparations containing 5% or less of benzoyl peroxide (That is 5% benzoyl peroxide products have gone to unclassified. The background to this change is given below)

Naproxen in divided preparations containing 250mg or less of naproxen per dosage unit in packs of 30 or less dosage units.

Background to the "Reverse Scheduling" of Benzoyl Peroxide

In making a decision to "reverse" or "down" schedule benzoyl peroxide the N.D.P.S.C. took advice from a TGA safety evaluator, reviewed an extensive list of current pharmaceutical references and received submissions from the pharmaceutical industry and pharmaceutical bodies.

Some of the key points in reaching the decision were:

- *Benzoyl peroxide has had extensive international use as an OTC since the 1960s*
- *The risk of human carcinogenesis from topical OTC application is minimal*
- *In relation to skin sensitization, a number of studies demonstrate a relatively low rate of severe irritant or allergic reactions in-use*
- *Benzoyl peroxide preparations were generally available in other countries with less restrictive scheduling than that currently applied in Australia*

- *Adverse reaction monitoring in New Zealand (where 5% benzoyl peroxide is available on general sale for a number of years) had not generated reports that were of substantial concern*

The PSA and Guild supported the rescheduling of 10% or less products to S2 (though not the 5% to unscheduled)

Schedule 3

New Entry

Mometasone in aqueous nasal sprays delivering 50mcg or less of mometasone per actuation when the maximum recommended daily dose is no greater than 200mcg and when packed in a primary pack containing 200 actuations or less, for the treatment of seasonal allergic rhinitis in adults and children 12 years and over.

Schedule 4

New entries in Schedule 4 include:

Becaplermin-(Regranex gel® from Janssen-Cilag) containing becaplermin 100mcg/g for the treatment of small neuropathic diabetic foot ulcers (<5cm²) which have demonstrated adequacy of perfusion. Becaplermin is a recombinant human platelet derived growth factor.

Dalfopristin and Quinupristin -(Synercid Powder® for injection in 500mg vials-Rhone-Poulenc Rorer Australis) for the treatment of suspected or proven methicillin-resistant Staphylococcus aureus or vancomycin-resistant Enterococcus faecium infections requiring intravenous therapy where other antibiotics are inappropriate.

Dofetilide-(Tikosyn capsules® from Pfizer) containing 125mcg, 250mcg, and 500mcg for the conversion to and maintenance of normal sinus rhythm in patients with persistent symptomatic atrial fibrillation or atrial flutter of more than one week's duration.

Etonogestrel-(Implanon sub-dermal implant® from Organon) containing etonogestrel 68mg for use as a contraceptive agent. The implant should be removed and replaced every 3 years.

Other Matters of Feedback and Importance

Narcotic Safes and the Safekeeping of Keys

Poisons Regulation 18 specifies the requirements for the storage of narcotics. The only types of safes approved for pharmacy storage are:

1. A substantial torch and drill resistant free-standing safe floor safe weighing at least 500 kilograms, bolted and glued to a concrete floor.
2. An in-floor torch and drill resistant safe. The Secretary has approved two models: the CMI collector in floor safe with TDR door and the Abel TDR in-floor safe.

Since the instituting of these standards there has been very little diversion of narcotic substances via pharmacy burglaries.

The regulation further requires that when a narcotic substance isn't being accessed that the authorized person is to "keep the enclosure securely locked and retain the key thereof either on his or her person or in a place not readily accessible to other persons." Narcotic keys are not to remain on pharmacy premises after-hours.

If you have any queries related to these requirements please contact Pharmaceutical Services Branch.

Emergency Orders and the Verification of Narcotic Orders

A pharmacist may supply a narcotic substance on the verbal instructions of a medical practitioner if, due to urgent circumstances, it is impracticable for the prescriber to write and forward the prescription before the substance is supplied (Regulation 15AA). The prescriber must then forward the prescription **within 24 hours of issuing the instruction**. Verification of the authenticity of this communication is essential. To ensure compliance and maintenance of accurate and up to date narcotic substance records, if a prescription has not been forwarded within 24 hours it may be necessary for a pharmacist to make contact with the prescriber.

In addition authentication when dispensing a narcotic substance is critical and the pharmacist must ensure that he/she is either familiar with the prescriber's writing or has verified the prescription directly with the prescriber.

Isopropyl Alcohol (Isopropanol, 2-Propanol)

Pharmaceutical Services receives inquiries from time to time regarding any restrictions that apply to isopropyl alcohol. Consistent with the national scheduling standard this compound is not scheduled in the Tasmanian Poisons List. The Australian Customs Service has advised that there is no impediment to a pharmacist supplying isopropyl alcohol. However, please exercise normal professional discretion in establishing that any purchaser has a legitimate need. The Martindale monograph advises that if ingested isopropyl alcohol produces intoxication similar to ethanol with more prominent adverse effects. About 15% of an ingested dose is metabolised to acetone. The lethal dose is reported to be about 250ml.

Toxicity of Diphenoxylate/ Atropine

A recent review of the scheduling of the diphenoxylate/atropine product (Lomotil®) has highlighted its toxicity in children; accidental overdosage can result in severe, even fatal respiratory depression. Children are particularly sensitive to both components of Lomotil and there seems to be no correlation between the dose ingested and the severity of toxicity. Symptoms can occur in children less than five years of age with as little as one tablet.

One Scottish paper found that in 67% of poisoning cases in children Lomotil had been prescribed for an adult relative. Please ensure that all patients receiving this compound appreciate the requirement for keeping medication out of the reach of children and that diphenoxylate/atropine should not be used for the treatment of diarrhoea in those under 12 years of age.

Oxycontin® Drug Codes

The codes for the Oxycontin products are:

Drug	Code
Oxycodone CR tablets 10mg (Oxycontin)	514
Oxycodone CR tablets 20mg (Oxycontin)	515
Oxycodone CR tablets 40mg (Oxycontin)	516
Oxycodone CR tablets 80mg (Oxycontin)	517