

Contact: Jim Galloway  
Phone: 03 6233 6471  
Fax: 03 6233 3904  
E-mail: james.galloway@dchs.tas.gov.au  
Mail: GPO Box 125B, Hobart, Tas. 7001.

## **Newsletter Number 19**

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### **INFORMATION CIRCULAR FOR PHARMACISTS IN TASMANIA**

## **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 1<sup>st</sup> December 2001. Below are detailed the more notable changes.

### **1. Schedule 2- New entries**

**DESLORATIDINE** in preparations for oral use.

**FOLIC ACID** for human therapeutic use **except** in preparations containing 500 micrograms or less of folic acid per recommended daily dose.

**FOLINIC ACID** for human therapeutic use **except** in preparations containing 500 micrograms or less of folinic acid per recommended daily dose.

***Background:** The entries for folic acid and folinic acid have been moved from Schedule 3 to Schedule 2- this will permit advertising of folic acid products and improved accessibility. There appears to be an inverse relationship between folic acid levels and neural tube defects (NTDs). Unfortunately the percentage of women of child-bearing age that are aware of the need for folic acid supplementation prior to and during pregnancy had remained low despite numerous campaigns initiated by health groups and the Australian government. There are 400-500 NTDs identified each year and it is estimated that two-thirds are preventable with adequate supplementation.*

### **2. Schedule 2 Amendments**

**IRON COMPOUNDS** (excluding iron oxides when present as an excipient, up to 1 per cent in undivided preparations or up to 10mg per dosage unit in divided preparations) for human internal use except:

- (a) when included in Schedule 4
- (b) in preparations when labelled with a recommended daily dose of more than 5mg but less than 24mg of iron when supplied in a pack each containing 600mg or less of iron; or
- (c) in other preparations when labelled with a recommended daily dose of 5mg or less of iron

***Background:** This amendment has allowed an increase in the iron content of non-scheduled iron products to less than 24mg. The toxicity risk has been managed by the*

*restriction to a 600mg pack content limit and the continued application of Therapeutic Goods Orders which require child resistant closures. The committee noted that a daily dose of around 24mg more closely meets the NH and MRC recommendations for the daily intake of iron.*

**PODOPHYLLOTOXIN** in preparations containing 0.5% or less of podophyllotoxin for human use for the treatment of warts except when in Schedules 3 or 4.

### **3. Schedule 3- Amendments**

**PODOPHYLLOTOXIN** in preparations containing 1 per cent or less of podophyllotoxin for human use for the treatment of warts except when in Schedules 2 or 4.

***Background:** The scheduling of podophyllum resin and podophyllotoxin has now been amended to list their use for the treatment of anogenital warts and for oral use in Schedule 4. In regards to the treatment of anogenital warts there was recognition that sexually transmitted diseases (STD) require medical assessment and management to exclude the presence of other STDs, ensure eradication of the disease and counselling in respect of hygiene and disease transmission.*

### **5. Schedule 4- New entries**

**COPPER COMPOUNDS** for human use except:

- (a) when separately specified in the schedules
- (b) in preparations for human internal use containing 5mg of less of copper per recommended daily dose; or
- (c) in other preparations containing 5 per cent or less of copper compound.

***Background:** A new entry has been established to cover the human use of copper compounds both orally and topically. Please note that the entry does not include copper metal.*

### **6. Schedule 4- Amendments**

**BORON** for human therapeutic use (excluding when present as an excipient):

- (a) in preparations for internal use containing more than 3 milligrams per recommended daily dose;
- (b) in glycerins and honeys of borax or boric acid;
- (c) in preparations for vaginal use;
- (d) in preparations for paediatric dermal use, being
  - (i) dusting powders; or
  - (ii) other preparations containing more than 0.35% boron; or
  - (iii) in other preparations for dermal use containing more than 0.35% of boron except antifungal preparations

***Background:** The committee has confirmed the need for restrictions on boron for human use. However, part (a) has been amended to allow for small oral doses of up to 3mg as this is well within the tolerable daily intake (TDI) for boron (the TDI equates to 28mg/day for a 70kg person). Boron is said to have a regulatory role in calcium and hence bone metabolism.*

**GUAIPHENESIN** for human therapeutic use except:

- (a) in oral liquid preparations containing 2 per cent or less of guaiphenesin; or
- (b) in divided preparations containing 200mg or less of guaiphenesin per dosage unit.

**Background:** This amendment (the entry has been moved to Schedule 4) has no regulatory impact on existing products. The TGA guidelines require products to carry a warning statement that they are not to be used in children less than two years of age without medical advice.

## 7. Schedule 6- Amendment

HYDROFLUORIC ACID (excluding its salts and derivatives) and admixtures that generate hydrofluoric acid, in preparations containing 1 per cent or less of hydrogen fluoride **except** when included in Schedule 5.

**Background:** As a result of concerns expressed by Tasmania to NDPSC, input from the Australian and New Zealand Burns Association and Poisons Information Centres, this amendment to hydrofluoric acid scheduling will restrict domestic products to a maximum concentration of 1%. Products above that strength will now appear in Schedule 7 and require a licence to obtain, possess and use. The Branch thanks pharmacists, their associations and pharmaceutical wholesalers for their co-operation in the early imposition from December 2000 of a voluntary withdrawal of Rustiban in the interests of public health.

## 8. Beta 2 agonists in Schedule 3 and recording requirements

From 1<sup>st</sup> September the Poisons List entries for the beta-2 agonists, salbutamol and terbutaline, have been amended to the entries shown below to provide for a greater choice of dry powder delivery systems in schedule 3 (the changes were advised in Circular 18 to pharmacies).

**SALBUTAMOL** as the only therapeutically active substance:

- (a) in metered aerosols delivering 100 micrograms or less of salbutamol per metered dose; or
- (b) in dry powders for inhalation delivering 200micrograms or less of salbutamol per dose.

**TERBUTALINE** as the only therapeutically active substance:

- (a) in metered aerosols delivering 250micrograms or less of terbutaline per metered dose; or
- (b) in dry powders for inhalation delivering 500micrograms or less of terbutaline per dose.

Please note that the requirements for the normal "S3R" recording of these products are unchanged (the recording requirements for recordable S3 drugs are specified separately in the Poisons Regulations and not in the Poisons Lists). The drugs currently requiring recording when in Schedule 3 are:

Aminophylline  
Dihydrocodeine in undivided preparations  
Salbutamol  
Terbutaline  
Theophylline

## **9. Iodine supplementation**

Subsequent to advice to pharmacists from Dr. Avner Misrachi in October this Branch has received queries from pharmacists regarding iodine supplementation. One issue raised was the provision of Lugol's iodine for supplementation. Advice from Dr. John Burgess, endocrinologist on the Thyroid Advisory Committee, and Judy Seal, State Nutrition Officer was:

1. Customers should be encouraged to follow the general dietary advice ie the consumption of bread produced with iodised salt, milk and fish.
2. The Lugol's preparation is a concentrated form of iodine and should not be recommended for supplementation other than on medical advice.
3. If a customer is eating a healthy well balanced diet supplements are not usually required. If the customer chooses to take a multivitamin supplement, make sure it has added iodine. A supplement providing iodine in the range of 75 to 90 micrograms per day would meet the requirements of adults and children.

Further information is available at the Department's Public Health website address [www.tas.gov.au/publichealth/iodine/](http://www.tas.gov.au/publichealth/iodine/)

Jim Galloway  
**Senior Pharmacist**