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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 (NDPSC), a number of amendments have been made to the Tasmanian Poisons List that take effect from the 8<sup>th</sup> September 2004. Below are detailed the more notable changes.

### 1. Schedule 2- New entry

**TRIAMCINOLONE** in aqueous nasal sprays delivering 50 micrograms or less of triamcinolone per actuation when the maximum recommended daily dose is no greater than 200 micrograms and when packed in a primary pack containing 120 actuations or less, for prophylaxis or treatment of allergic rhinitis for up to 6 months in adults and children 12 years of age and over.

***Background:** After a review of the data submitted the committee agreed to include intranasal triamcinolone in Schedule 2. This is consistent with the scheduling of the fluticasone, budesonide and mometasone intranasal preparations. Please note that due to concerns regarding growth retardation with intranasal steroid therapies in children under 12 years, use in younger persons requires medical management and therefore these products remain in Schedule 4 for this age group.*

### 2. Variation to antihistamine entries in Schedule 2

NDPSC has reviewed the scheduling of antihistamines and endorsed the following principles:

- Antihistamines and preparations with the potential for serious abuse be included in Schedule 4
- Single-active preparations of antihistamines with a high sedative potential be included in Schedule 3
- Single-active preparations of 'non-sedating' antihistamines and specified combination preparations of antihistamines be included in Schedule 2.

**Please note that the regulatory impact of the Poisons List amendments on existing preparations will be minimal. Also note that “Mersyndol® type” analgesic products remain in Schedule 3. Schedule 2 entries provide for the inclusion of products for the treatment of coughs, colds and influenza, travel sickness and for some topical applications- there is no provision for preparations for the treatment of pain.**

The new entries in Schedule 2 read:

**ANTI HISTAMINE (1)\*** when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:

- (a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
- (b) in a day-night pack containing antihistamine (1) in the bed-time dose,

**except** in preparations for the treatment of children two years of age or less.

**\*ANTI HISTAMINE (1) is brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenpyraline, doxylamine, trimeprazine or triprolidine**

**ANTI HISTAMINE (2)\*\***

- (a) in primary packs of 10 doses or less, for the prevention or treatment of motion sickness; or
- (b) when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:
  - (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
  - (ii) in a day-night pack containing antihistamine (2) in the bed-time dose,

**except** in preparations for the treatment of children two years of age or less.

**\*\*ANTI HISTAMINE (2) is diphenhydramine or promethazine**

**PHENIRAMINE:**

in eye drops; or

- (a) when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:
  - (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
  - (ii) in a day-night pack containing pheniramine in the bed-time dose,

**except** in preparations for the treatment of children two years of age or less.

### **THENYLDIAMINE:**

- (a) in nasal preparations for topical use; or
  - (b) when combined with one or more other therapeutically active substances in oral preparations for the treatment of symptoms of coughs, colds or influenza when:
    - (i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or
    - (ii) in a day-night pack containing thenyldiamine in the bed-time dose,
- except** in preparations for the treatment of children two years of age or less.

Please also note that the **CODEINE** entry in Schedule 2 has been amended to allow codeine/antihistamine combinations consistent with the above entries.

## **4. Variation to fluoride entry in Schedule 2**

**FLUORIDES** for human use (except in preparations containing 15 mg/kg or 15 mg/L or less of fluoride ion):

- (a) as sodium fluoride, in preparations for ingestion containing 2.2 mg or less of sodium fluoride per dosage unit; or
- (b) in preparations for topical use containing 2.5 per cent or less of fluoride ion **except**:
  - (i) pastes, powders or gels for the cleaning of teeth, included in Schedule 3;
  - (ii) pastes, powders or gels for the cleaning of teeth, containing 1000 mg/kg or less of fluoride ion; or
  - (iii) other dental hygiene products containing 220 mg/kg or 220 mg/L or less of fluoride ion, in packs containing not more than 120 mg total fluoride, fitted with a child-resistant closure and labelled with warnings to the following effect:
    - (A) Do not swallow; and
    - (B) Do not use [this product/name of product] in children six years of age or less.

**Background:** (b)(iii) was amended to allow exemption from scheduling of mouthwashes at 0.022% fluoride or less provided there was a limitation on the pack size (no greater than 120mg), the products were fitted with a child resistant closure and the products were labelled as not recommended for use in children under six years of age.

## **2. Quinine scheduling**

### **Schedule 3 entry**

**QUININE-** Deleted

#### **Schedule 4- Amendment**

**QUININE** for internal use **except** in preparations containing 50mg or less of quinine per recommended daily dose.

***Background:** The Australian Drug Evaluation Committee (ADEC) considered a proposal from the Adverse Drug Reaction Advisory Committee (ADRAC) to remove all quinine containing products from the register of therapeutic goods except for those indicated for the treatment of malaria. ADEC endorsed that recommendation and concluded that the risk/benefit ratio of quinine for cramps is too unfavourable to justify its use for that indication.*

**PHARMACY MANAGERS- PLEASE CIRCULATE TO ALL PHARMACISTS IN YOUR EMPLOYMENT.**

*(Please note that this and other circulars are available on the DHHS website at [www.dhhs.tas.gov.au/publichealth/pharmaceuticals/](http://www.dhhs.tas.gov.au/publichealth/pharmaceuticals/))*

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