



Changes to Poisons Act Schedules

Effective 1st September 2008

TO BE USED AS A GUIDE ONLY

Please refer to the Standard for the Uniform Scheduling of Drugs and Poisons
(SUSDP) No 23 Amendment 1

SCHEDULE 2 – AMENDMENTS

Fluorides – see table on next page.

SCHEDULE 3 – AMENDMENTS

Sedating antihistamines (brompheniramine, chlorpheniramine, dexchlorpheniramine, diphenhydramine, doxylamine) – the supply of any of these antihistamines for the treatment of children under 2 years of age is now excluded from both Schedule 2 and Schedule 3. The supply of all sedating antihistamines (including pheniramine and triprolidine) for use in this age group now requires a prescription.

Fluorides – see table on next page.

SCHEDULE 4 – NEW ENTRIES

Dirilotapide – a new veterinary medicine for the treatment of obesity in dogs. Dirilotapide works by selectively inhibiting microsomal triglyceride transfer protein (MTP). MTP is pivotal for the absorption and distribution of fat, and MTP inhibition reduces intestinal fat absorption.

Panitumumab – a recombinant human monoclonal antibody that binds to the epidermal growth factor receptor (EGFR). It is used in the treatment of EGFR-expressing metastatic colorectal cancer after failure of other standard chemotherapy regimens.

SCHEDULE 4 – AMENDMENTS

Fluorides – see table on next page.

Other Reminders

Beware of Faxed Prescriptions!

Recently, the Department has received a number of reports of forged prescriptions for Schedule 8 medicines where the “prescription” has been transmitted by facsimile. The person wishing to fraudulently obtain the Schedule 8 medicine will often telephone the pharmacy to explain that they cannot attend their doctor’s surgery but will organise for the surgery to fax through a “prescription”. Sometimes the original prescription will be genuine but copies will have been faxed to multiple pharmacies. The person trying to obtain the S8 medicine may pretend to be a receptionist from a doctor’s surgery and may even provide a telephone number for the “surgery” so the “prescription” can be “verified”. Any telephone number provided during this type of telephone call or written on a faxed prescription should always be independently verified and should not assumed to be genuine.



Remember: a faxed prescription is not a compliant prescription! Only an ORIGINAL prescription should be dispensed. However, a doctor may fax a prescription to confirm directions given by him/her to the pharmacist by telephone provided the original prescription is dispatched to the pharmacy within 24 hours.

Change of Pharmacy Ownership

If a change in ownership of a pharmacy requires a change to the licence holder, pharmacists are reminded that a **minimum of 5 working days** is required for the processing of the new licence. These five days commence once the Department has been notified by the Pharmaceutical Council that the pharmacy has been registered under the *Pharmacy Act 1964*. The proposed licence holder is also required to submit a completed application form (Licence to Sell a Poison by Retail) and pay the appropriate fee. A new application to participate in the Community Program for Opioid Pharmacotherapy (C-POP) is also required for any participating pharmacy if there is a change in ownership.

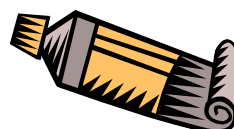




Fluoride Scheduling

The scheduling of fluoride, including toothpastes and mouthwashes, has been revised in an attempt to update and simplify the requirements. The aim was to maintain public health and safety from the point of view of both toxicity from acute ingestion and the potential for the development of fluorosis. The NDPSC also considered current recommendations for prevention of dental caries and the exposure of the Australian population to fluoride via drinking water. See *SUSDP No 23 Amendment 1* for full details of scheduling.

Preparation	Schedule
Tablets (and other preparations for ingestion), up to 0.5 mg fluoride ion per tablet	Schedule 2 Note: The maximum strength of oral preparations at S2 has now been halved (previously maximum was 2.2 mg of sodium fluoride per dosage unit which is equivalent to 1 mg of fluoride ion).
Mouthwashes (and other liquid preparations for topical use), concentration of 15 mg/kg or less of fluoride ion	Unscheduled
Mouthwashes (and other liquid preparations for topical use), concentration of 220 mg/kg or less of fluoride ion (but more than 15 mg/kg)	Unscheduled if in a <i>small bottle</i> (maximum total fluoride ion content of pack is up to 120 mg), with a child resistant closure (CRC), labelled with warnings: "Do not swallow" and "Do not use in children 6 years of age or less".
Mouthwashes (and other liquid preparations for topical use), concentration of 1000 mg/kg or less of fluoride ion (but more than 15 mg/kg).	Schedule 2 Must be in a container with a CRC and labelled with warnings: "Do not swallow" and "Do not use in children 6 years of age or less".
Mouthwashes (and other liquid preparations for topical use), concentration > 1000 mg/kg but ≤ 5500 mg/kg of fluoride ion	Schedule 3 Must be in a container with a CRC.
Toothpastes (and other non-liquid preparations for topical use such as powders and gels), ≤ 1000 mg/kg fluoride ion	Unscheduled
Toothpastes (and other non-liquid preparations for topical use such as powders and gels), > 1000 mg/kg but ≤ 1500 mg/kg fluoride ion	Unscheduled provided have warning labels to indicate they must not be swallowed and must not be used in children aged 6 or under. Otherwise these preparations are in <i>Schedule 3</i> . Note: this change raises the concentration of fluoride ion that may be used in toothpastes which may be exempted from scheduling (with certain warning labels) from 1000 mg/kg to 1500 mg/kg.
Toothpastes (and other non-liquid preparations for topical use such as powders and gels), > 1500 mg/kg but ≤ 5500 mg/kg fluoride ion	Schedule 3
Other preparations for human use (unless included in or expressly excluded from S2 or S3)	Schedule 4 Note: fluoride does also appear in Schedule 5 and Schedule 6 for non-human uses



Please note: Preparations that would normally be in both Schedule 2 and Schedule 3 are exempt from scheduling if they are supplied to a registered dental professional (this includes a dentist, dental therapist, dental hygienist or school dental therapist).

