



Changes to Poisons Act Schedules

Effective 1st September 2009

TO BE USED AS A GUIDE ONLY

Please refer to the Standard for the Uniform Scheduling of Drugs and Poisons
(SUSDP) No 24 Amendment 1

SCHEDULE 2 – AMENDMENTS

Hydroquinone – the concentration in hair preparations which are exempt from S2 (to unscheduled) has been reduced from 1% to 0.3% or less of hydroquinone. The same concentration is allowed in countries of the European Union.

SCHEDULE 2 – NEW ENTRY

Guaiphenesin – in a controlled release dosage form containing not more than 1200mg of guaiphenesin. Recommended daily dose must not exceed 2400mg and is not to be used in children under 12.

SCHEDULE 4 – AMENDMENTS

Guaiphenesin – amended to include 'except when included in Schedule 2' (see above). Previous exclusions from S4 still apply.

SCHEDULE 4 – NEW ENTRIES

Alpha₁-proteinase inhibitor (A1-PI) (human) – a blood modifier agent prepared from pooled human plasma. Used as replacement therapy in patients with emphysema who have congenital alpha₁-antitrypsin deficiency. Administered intravenously.

Ambrisentan – an endothelin receptor antagonist with selectivity for the endothelin type-A (ET-A) receptor. Similar mechanism of action to bosentan and sitaxentan. Indicated for pulmonary arterial hypertension. Listed in Appendix D, where prescribing is restricted to specialist physicians and pregnancy must be excluded before use and for 3 months after completing treatment.

Bazedoxifene – a selective oestrogen receptor modulator (SERM). Indicated for the prevention and treatment of postmenopausal osteoporosis.

Cilostazol – a quinolone derivative and inhibitor of cellular phosphodiesterases. Indicated for the management of intermittent claudication.

SCHEDULE 4 – NEW ENTRIES continued

Dapoxetine – a rapidly absorbed, short-acting SSRI developed specifically for treatment for premature ejaculation.

Etravirine – a non-nucleoside reverse transcriptase inhibitor (NNRTI) with activity against HIV-1. Used in combination with other antiretrovirals to treat HIV-1 infection in treatment-experienced patients, who have evidence of viral replication and resistance to NNRTI and other antiretrovirals.

Gemtuzumab ozogamicin – a recombinant humanised monoclonal antibody conjugated with calicheamicin, a cytotoxic antibiotic. Administered intravenously for treatment of acute myeloid leukemia.

Methylnaltrexone – a peripherally-acting antagonist of opioid mu-receptors, targeting binding sites in tissues such as the gastrointestinal tract. Used to treat opioid related constipation in palliative care patients who have had insufficient response using laxatives.

Phosphodiesterase Type 5 Inhibitors except when separately specified in schedules – class entry included in response to reports of adulteration of complementary medicines with various PDE5 inhibitors. Other drugs in this class include sildenafil, tadalafil and vardenafil.

Rivaroxaban – an oral direct inhibitor of activated factor Xa, a new class of anticoagulants. Indicated for the short prevention of venous thrombosis in patients who have undergone major lower limb surgery (eg total hip or knee replacement).

Sugammadex – the first selective relaxant binding agent. Used to reverse the action of non-depolarising muscle relaxants used in general anaesthesia, such as rocuronium and vecuronium.

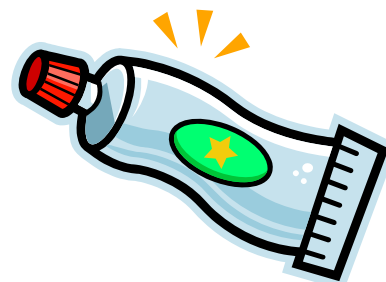




Oral Hygiene Products containing Diethylene Glycol or Ethylene Glycol

Toothpastes and similar products manufactured overseas may contain the sweet-tasting chemicals, diethylene glycol (DEG) and ethylene glycol. In particular, diethylene glycol has been substituted for glycerol in both toothpastes and oral pharmaceutical mixtures. Medium to long term exposure to diethylene glycol at significant levels from these type of preparations may create unacceptable risks, particularly to children and individuals with kidney and liver disease. These chemicals are appropriately used as antifreeze agents and in the industrial setting as solvents and precursors for various polymers.

The scheduling of diethylene glycol and ethylene glycol has been reviewed in light of the potential toxicity of these compounds. Toothpastes or mouthwashes containing only up to and including 0.25% of diethylene glycol or ethylene glycol may be exempt from the schedules. Toothpastes or mouthwashes containing more than 0.25% of ethylene glycol are now listed in Appendix C of the SUSDP. Appendix C contains substances which are considered to be of such danger to human health to warrant prohibition of sale, supply or use. In March 2009, the regulator of cosmetics, the Australian Competition and Consumer Commission (ACCC) banned the sale of toothpaste containing more than 0.25% by weight of diethylene glycol.



The SUSDP is available online....

The SUSDP and its amendments are available online at the ComLaw FRLI website.

Follow the links available from the National Drugs and Poisons Schedule Committee (NDPSC) section of the TGA website:

www.tga.gov.au/ndpsc/susdp.htm

What can a dentist prescribe?

Dentists may prescribe any Schedule 4 medicine, which may or may not be included as a Pharmaceutical Benefits Scheme (PBS) item, provided it is for the treatment of a dental condition. They may only prescribe Schedule 8 medicines which are listed on the PBS under the heading 'Preparations which may be prescribed by participating dental practitioners for dental treatment only'. A dentist may only prescribe 7 days of treatment with a S8 medicine at a time. If they wish to prescribe a S8 medicine for the same patient on a number of occasions, they must seek authorisation from the Department of Health if the prescribing would result in more than 60 days treatment over a 12 month period.



What can a veterinary surgeon prescribe?



A vet may prescribe any Schedule 4 or 8 medicine for the treatment of an animal. Prescriptions must be clearly endorsed that the medicine is for animal treatment only. Schedule 8 prescriptions from vets are not required to include the date of birth of the animal but must include the name and address of the person caring for the animal. A vet may not write repeats on S8 prescriptions.

