Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Consultation: Proposed amendments to the Poisons Standard – ACMS #49, ACCS #42 and Joint ACMS-ACCS #43 meetings, March 2026

23 December 2025

Confidentiality

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About this consultation

Subdivision 3D.2 of the Therapeutic Goods Regulations 1990 (**the Regulations**) sets out the procedure to be followed where the Secretary receives an application under section 52EAA of the Therapeutic Goods Act 1989 (**the Act**) to amend the current Poisons Standard or decides to amend the Poisons Standard on his or her own initiative and decides to refer the proposed amendment to an expert advisory committee. These include, under regulation 42ZCZK, that the Secretary publish (in a manner the Secretary considers appropriate) the proposed amendment to be referred to an expert advisory committee, the committee to which the proposed amendment will be referred, and the date of the committee meeting. The Secretary must also invite public submissions to be made to the expert advisory committee by a date mentioned in the notice as the closing date, allowing at least 20 business days after publication of the notice.

In accordance with regulation 42ZCZK of the Regulations, the Secretary invites public submissions on scheduling proposals referred to the **March 2026** meetings of the Advisory Committee on Medicines Scheduling (ACMS), Advisory Committee on Chemicals Scheduling (ACCS) and (Joint) Advisory Committee on (Medicines/Chemicals) Scheduling (Joint ACMS-ACCS). Submissions must be received by close of business **29 January 2026**.

Submissions should be provided through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of these two committees.

This consultation closes on 29 January 2026.

We aim to provide documents in an accessible format. If you're having problems using this document, please contact medicines.scheduling@health.gov.au.

1 Proposed amendment referred for scheduling advice to ACMS meeting #49

1.1 Melatonin

Proposal

The applicant has proposed to amend the current Poisons Standard in relation to melatonin. Under the proposal, the Pharmacist-only medicine (Schedule 3) entry for melatonin would be deleted, and a Pharmacy medicine (Schedule 2) entry for the substance would be created. The new Schedule 2 entry would expand melatonin's dosage forms, strengths and access for those aged 18 years and over for monotherapy for the treatment of primary insomnia. The Appendix H entry which allows for melatonin to be advertised while included in Schedule 3 would also be deleted as Schedule 2 medicines are permitted to be advertised.

CAS number

73-31-4

Alternative names

N-acetyl-5-methoxytryptamine

Applicant

Private applicant

Proposed Scheduling

Melatonin is currently listed in Schedules 3 and 4 of the Poisons Standard as follows:

Schedule 3

MELATONIN in:

(a) modified release tablets containing 2 mg or less of melatonin for monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep for adults aged 55 or over, in packs containing not more than 30 tablets; or

(b) immediate release preparations containing 5 mg or less of melatonin for the treatment of jet lag in adults 18 years and over, in a primary pack containing no more than 10 dosage units.

Schedule 4

MELATONIN for human use except when included in Schedule 3.

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MELATONIN

Schedule 3

Schedule 4

Appendix H, clause 1

The applicant's proposed amendments to the Poisons Standard are[1]:

Schedule 3 – Delete entry

~~MELATONIN in:~~

~~(a) modified release tablets containing 2 mg or less of melatonin for monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep for adults aged 55 or over, in packs containing not more than 30 tablets; or~~

~~(b) immediate release preparations containing 5 mg or less of melatonin for the treatment of jet lag in adults 18 years and over, in a primary pack containing no more than 10 dosage units~~

Schedule 4 – Amend entry

MELATONIN for human use except when included in ~~Schedule 3~~ Schedule 2

Schedule 2 – New entry

MELATONIN in:

(a) modified release dose units containing 2 mg or less of melatonin for monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep for adults aged 18 or over, in packs containing not more than 30 days' supply; or

(b) immediate release dose units containing 3 mg or less of melatonin for monotherapy for the short-term treatment of primary insomnia characterised by poor quality of sleep for adults aged 18 or over, in packs containing not more than 30 days' supply; or

(c) immediate release dose units containing 5 mg or less of melatonin for the treatment of jet lag in adults 18 years and over, in a primary pack containing no more than 10 days' supply.

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Melatonin

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Appendix H, Clause 1 – Schedule 3 medicines permitted to be advertised – Delete entry

Item	Column 1 Poison
~~28~~	~~MELATONIN~~

Background

Melatonin is an endogenous hormone that regulates the sleep-wake cycle in both humans and animals. In the body it is produced by the pineal gland, which receives input from the suprachiasmatic nucleus of the hypothalamus.[2] Secretion of melatonin decreases following exposure to light and increases in darkness.[3] Melatonin acts on the MT1 and MT2 receptors – which are widely expressed across the central nervous system – and elicits sleep-inducing effects such as drowsiness and a drop

[1] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

[2] Ma MA, Morrison EH (2023). Neuroanatomy, Nucleus Suprachiasmatic. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing. https://www.ncbi.nlm.nih.gov/sites/books/NBK546664/

[3] Savage RA, Zafar N, Yohannan S, Miller JM (2024). Melatonin. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing. https://www.ncbi.nlm.nih.gov/books/NBK534823/

in body temperature. Exogenous supplementation has become increasingly used for the treatment of various sleep disorders.

In Australia, melatonin is available as a Prescription-only medicine (Schedule 4), except for the treatment of primary insomnia in adults aged 55 and over (in a primary pack containing not more than 30 tablets), or for the treatment of jet lag in adults aged 18 or over (in a primary pack containing not more than 10 days' supply) – both of which are available as Pharmacist-only medicines (Schedule 3).

The final decision for the new Schedule 3 melatonin entry was published in 2020. The decision was made to include only the currently specified indications for approved melatonin products to ensure safe and evidence-based use of the medicine.

Summary of applicant's reasons for the proposal

The applicant reasoning for their proposal is on the basis that melatonin has a favourable safety profile, low toxicity and mild, self-limiting side effects. The applicant claims that the proposal will improve public safety by deterring consumers from purchasing unapproved, substandard melatonin products online.

The applicant's proposal will also bring Australia's regulation of melatonin in line with that of New Zealand, which was amended as of October 2025 to allow for the supply of the substance to adults aged 18 or over, without the need for a prescription.[4] Furthermore, the applicant is seeking to alter the wording of entries from 'tablets' to 'dose unit preparations'. This change is being sought to allow for flexibility in the concentration, duration and delivery of melatonin (i.e. to allow for preparations such as pastilles, capsules etc.)

Key uses / expected use

Melatonin is typically used as a monotherapy indicated for the treatment of primary insomnia, jet lag and shift worker syndrome. It has also been reported as a potential option in the treatment of nicotine or benzodiazepine withdrawal, as well as cluster headache and delayed sleep phase syndrome.[5]

Australian regulations

- According to the TGA Ingredient Database, melatonin is available for use as:
  - An active ingredient in:
    - Biologicals, Export Only, Over the Counter and Prescription Medicines.
  - An excipient ingredient in:
    - Biologicals, Devices, Prescription Medicines
- Melatonin is not available as an equivalent ingredient in any application.
- As of 3 December 2025, there were 59 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain melatonin as an active ingredient. These include 34 prescription and 17 non-prescription medicines.
- Melatonin is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies melatonin as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3

[4] Medsafe (2025) Applications for approval of melatonin medicines

[5] Melatonin: Uses, Interactions, Mechanism of Action | DrugBank Online

Melatonin	B3	Central Nervous System	Hypnotics and sedatives	
Category B3 – Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to melatonin to be included on the labelling:

Substance	Conditions	Required statements
Melatonin	In modified-release tablets containing 2 mg or less of melatonin	• Do not use if: - you are under 55 years of age - you are taking any other medicines for sleep - you have liver problems - you are pregnant or breastfeeding. • Unless a doctor has told you to, do not use: - for more than 3 weeks - if you have kidney problems - if you have an autoimmune disease. • Consult a pharmacist or doctor before use if you are taking other medicines regularly. • Do not drink alcohol while taking this medicine. • This medication may cause drowsiness. If affected do not drive or operate machinery.

- As of 19 November 2025, there were 115 reports of adverse events for products containing melatonin as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 68 reports where melatonin was the single suspected medicine. There were 3 reports of deaths associated with melatonin use, although 2 of the 3 deaths were associated with deliberate misuse of the product. Many cases have been from ingestion by children.
- As of 3 December 2025, there was 1 product containing melatonin as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009-2019 there were no adverse experiences recorded for melatonin in the APVMA Adverse Experience Reporting Program database (AERP).
- Melatonin is included by Australian Industrial Chemicals Introduction Scheme (AICIS) on the Australian Inventory of Industrial Chemicals (Inventory).

International regulations

- In Canada, melatonin is classified as a Natural Health Product and is available over-the-counter for adults only. As of 9 September 2025, melatonin (or its salts) has been added to the Prescription Drug List, specifically when sold for the treatment of insomnia in those ages 2 to under 18 years of age with Autism Spectrum Disorder and/or Smith-Magenis Syndrome.[6] The Health Canada Drug Product Database lists 2 prescription products

[6] Notice of amendment: Addition of melatonin to the Prescription Drug List - Canada.ca

containing melatonin for human use and 1 non-prescription product containing melatonin for veterinary use.

- New Zealand will change its listing of melatonin to expand their listing to enable approval of products that may be supplied to adults aged 18 years and over without a consultation with a doctor or pharmacist, for short-term treatment of primary insomnia.
- The New Zealand Medsafe Medicines Classification Database currently lists melatonin as follows:

Substance	Conditions (if any)	Classifications
Melatonin	**except** when supplied in medicines for oral use containing 3mg or less per immediate release dose unit, or 2mg or less per modified release dose unit, when sold in the manufacturers original pack that has received consent from the Minister of Health or the Director General for the treatment of primary insomnia for adults aged 55 years or older for up to 13 weeks by a registered pharmacist; **except** when specified elsewhere in this schedule.	Prescription
Melatonin	when supplied in medicines for oral use in immediate release preparations containing 5mg or less per dose unit for the treatment of jet lag in adults aged 18 or over, containing not more than 10 days' supply, in the manufacturers original pack that has received consent from the Minister or Director-General for sale as a pharmacy only medicine; when supplied in medicines for oral use containing 3mg or less per immediate release dose unit, or 2mg or less per modified release dose unit, for the treatment of primary insomnia for adults aged 18 years or older, containing not more than 30 days' supply, in the manufacturers original pack that has received consent from the Minister or Director-General.	Pharmacy Only

- The United Kingdom Electronic Medicines Compendium lists 35 prescription-only medicines containing melatonin.
- The European Commission Union Register of medicinal products lists 3 entries containing melatonin for human use.
- In Ireland, the Health Products Regulatory Authority lists 8 authorised products that contain melatonin for human use.
- In the United States, melatonin is widely available over the counter as a dietary supplement. The United States Food and Drug Administration does not regulate melatonin; as such, it is not included in the United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) or The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

1.2 First-generation sedating antihistamines

Proposal

The Department of Health, Disability and Ageing has proposed to amend the current Poisons Standard so that all oral first-generation sedating antihistamine products currently classified as Pharmacy medicines (Schedule 2, when formulated for use in children under 12 years of age, are rescheduled to Pharmacist-only medicine (Schedule 3).

This change aims to ensure pharmacist oversight for all oral first-generation sedating antihistamines, given the cumulative safety concerns identified, particularly in children. These medicines offer limited therapeutic benefit, and inappropriate use in paediatric populations has been associated with serious adverse outcomes, including psychiatric and central nervous system effects.

The substances in this proposal include alimemazine, brompheniramine, chlorphenamine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine, triprolidine, and dimenhydrinate.

CAS number

Alimemazine: 84-96-8

Brompheniramine: 86-22-6

Chlorphenamine: 132-22-9

Dexchlorpheniramine: 25523-97-1

Diphenhydramine: 58-73-1

Doxylamine: 469-21-6

Pheniramine: 86-21-5

Promethazine: 60-87-7

Triprolidine: 486-12-4

Dimenhydrinate: 523-87-5

Alternative names

Alimemazine: Alimemazine tartrate (Trimeprazine)

Brompheniramine: Brompheniramine maleate

Chlorphenamine: Chlorpheniramine: Chlorpheniramine maleate

Dexchlorpheniramine: Dexchlorpheniramine maleate, Dexchlorphenamine

Diphenhydramine: Diphenhydramine hydrochloride

Doxylamine: Doxylamine succinate

Pheniramine: Pheniramine maleate

Promethazine: Promethazine hydrochloride

Triprolidine: Triprolidine hydrochloride

Dimenhydrinate: Diphenhydramine 8-chlorotheophyllinate

Chlorphenamine: Chlorpheniramine maleate (Chlorpheniramine)

Proposed Scheduling

There is substantial consistency across the Poisons Standard entries for the sedating antihistamines in this proposal - with consistent wording regarding age restrictions, currently excluding use in children under 2 years of age. However, pheniramine, promethazine, and dimenhydrinate have significant differences as their entries include additional conditions related to product type and pack size.

To simplify this notice, the proposed scheduling for all the substances (excluding pheniramine, promethazine, and dimenhydrinate) is modelled on the wording used for alimemazine, which is provided below as an example.

Due to the differences in the Poisons Standard entries, the proposed amendments for pheniramine, promethazine, and dimenhydrinate are also presented.

Alimemazine (trimeprazine)

Schedule 4

ALIMEMAZINE **except** when included in Schedule 2 or 3.

Schedule 3

ALIMEMAZINE:

(a) in solid oral preparations except when included in Schedule 2; or

(b) in liquid oral preparations containing 10 mg or less of alimemazine per 5 mL;

except in preparations for the treatment of children under 2 years of age.

Schedule 2 – Amend entry

ALIMEMAZINE when combined with one or more other therapeutically active substances in solid oral preparations when:

(a) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(b) in a day-night pack containing alimemazine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper;

except in preparations for the treatment of children under ~~2~~12 years of age.

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ALIMEMAZINE

cross reference: TRIMEPRAZINE

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Schedule 2

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Pheniramine

Schedule 4

PHENIRAMINE **except** when included in Schedule 2 or 3

Schedule 3

PHENIRAMINE in oral preparations **except**:

(a) when included in Schedule 2; or

(b) for the treatment of children under 2 years of age.

Schedule 2 – Amend entry

PHENIRAMINE:

(a) in eye drops; or

(b) when combined with one or more other therapeutically active substances in oral preparations 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 where the day and night doses are in the same immediate container or immediate wrapper;

except in preparations for the treatment of children under ~~2~~12 years of age.

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Promethazine

Schedule 4

PROMETHAZINE **except** when included in Schedule 2 or 3.

Schedule 3

PROMETHAZINE in oral preparations **except**:

(a) when included in Schedule 2; or

(b) in preparations for the treatment of children under 2 years of age.

Schedule 2 – Amend entry

PROMETHAZINE in oral preparations:

(a) in a primary pack containing 10 dosage units or less for the prevention or treatment of motion sickness; or

(b) when combined with one or more other therapeutically active substances when:

(i) at least one of the other therapeutically active substances is a sympathomimetic decongestant; or

(ii) in a day-night pack containing promethazine in the bed-time dose where the day and night doses are in the same immediate container or immediate wrapper;

except in preparations for the treatment of children under ~~2~~12 years of age.

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PROMETHAZINE

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Dimenhydrinate

Schedule 4

DIMENHYDRINATE **except** when included in Schedule 2 or 3.

Schedule 3

DIMENHYDRINATE in oral preparations **except** when included in Schedule 2.

Schedule 2 – Amend entry

DIMENHYDRINATE in primary packs of 10 doses or less for the prevention or treatment of motion sickness, **except** in preparations for the treatment of children under ~~2~~12 years of age.

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DIMENHYDRINATE

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Background

First-generation antihistamines, introduced in the 1940s, act on histamine receptors and readily cross the blood brain barrier, which can lead to sedation. These medicines are still widely used for allergic conditions such as rhinitis and urticaria, as well as secondary indications including insomnia, nausea, and motion sickness.

Unlike second-generation antihistamines developed in the 1980s, first-generation agents are associated with more pronounced sedative and anticholinergic effects. While these properties can provide short-term symptom relief, they also increase the risk of adverse outcomes, particularly in children and older adults.[7]

Sedating antihistamines available in Australia include alimemazine, brompheniramine, chlorphenamine, diphenhydramine, doxylamine, pheniramine, promethazine, and dimenhydrinate.

First-generation antihistamines can cause dose-dependent sedation and anticholinergic effects, and large ingestions may lead to serious complications such as anticholinergic delirium, seizures, cardiovascular abnormalities, and postural hypotension. Accidental ingestions in children often result in mild sedation or vomiting, but higher doses can cause severe toxicity, including hyperactivity and impaired consciousness. Furthermore, these medicines are sometimes misused for non-medical purposes or as part of polysubstance use, increasing the risk of harmful outcomes.[8]

In Australia, oral sedating antihistamines are not recommended for children under 2 years of age due to the risk of serious adverse effects, including profound sedation, respiratory depression, and anticholinergic toxicity. For paediatric use, some products such as Phenergan (promethazine), Periactin (cyproheptadine), and Polaramine (dexchlorpheniramine) are already classified as Pharmacist-only medicines (Schedule 3), requiring pharmacist oversight. However, a small number

[7] Therapeutic Goods Administration. (13 July, 2022). First-generation antihistamines – winter warning. TGA. www.tga.gov.au/safety/safety-monitoring-and-information/safety-alerts/first-generation-antihistamines-winter-warning

[8] Therapeutic Guidelines. (published August 2020). Sedating antihistamines. In Toxicology and toxinology. Therapeutic Guidelines. Retrieved December 19, 2025

remain available over the counter as Pharmacy medicines (Schedule 2), including Demazin Kids 6+ Cough and Cold Relief (brompheniramine), Demazin Kids 6+ Cold Relief Blue Syrup (chlorphenamine), and Paedamin Decongestant Antihistamine Liquid (diphenhydramine). Vallergan (alimemazine) was previously available but has been discontinued since January 2020.

Summary of applicant's reasons for the proposal

The recommendation to up-schedule all oral first-generation sedating antihistamines when formulated for use in children under 12 years of age from Pharmacy medicine (Schedule 2) to Pharmacist-only medicine (Schedule 3) in the Poisons Standard follows cumulative safety concerns and expert advice indicating that these medicines may pose significant risks when supplied without pharmacist intervention. The proposed change applies to oral preparations containing alimemazine (trimeprazine), brompheniramine, chlorphenamine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine, triprolidine, and dimenhydrinate.

In 2009, the TGA reviewed over-the-counter cough and cold medicines for children aged 2–12 years and found safety concerns and lack of efficacy for first-generation antihistamines. The Advisory Committee on Medicines (ACM) supported further restrictions, however, the delegate decided at that time that risks could be managed through labelling and registration rather than scheduling changes.

In January 2022, the ACM reviewed use in children aged 2–5 years and advised that there is no evidence of efficacy for coughs, colds, or allergic indications in this age group; recommended non-sedating antihistamines for allergy treatment; and concluded that first-generation sedating antihistamines should be at least Pharmacist-only medicines (Schedule 3), with products for children aged 2–5 years discontinued and removed from the ARTG.[9]

Further safety actions were implemented in 2024 when the Product Information and Consumer Medicine Information for Phenergan (promethazine) were updated to extend the contraindication from children under 2 years to under 6 years, add warnings for psychiatric and central nervous system (CNS) adverse events such as aggression, hallucination, and psychomotor hyperactivity, and include overdose risks such as reversible intellectual disability and cognitive deficits. These changes followed a sponsor safety evaluation confirming a causal association between promethazine and CNS/psychiatric risks in children aged 2–5 years.[10]

The TGA's assessment concluded that first-generation sedating antihistamines present more potential for harm than benefit when used without health professional oversight, and availability as a Pharmacy medicine (Schedule 2) without pharmacist intervention poses higher risk, especially for children. Based on ACM recommendations and subsequent TGA review, this notice proposes up-scheduling all oral first-generation sedating antihistamines to Pharmacist-only medicine (Schedule 3).

Key uses / expected use

Allergic conditions, itch, nausea and vomiting, motion sickness, cough and cold preparations (often combined with other drugs), sleep (due to sedative effect)

Australian regulations

Alimemazine

- According to the TGA Ingredient Database, alimemazine is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines

[9] Therapeutic Goods Administration. (2 November 2022). ACM meeting statement, Meeting 31, 3–4 February 2022. www.tga.gov.au/resources/publication/meeting-statements/acm-meeting-statement-meeting-31-3-4-february-2022

[10] Therapeutic Goods Administration. (2024, November 19). Promethazine hydrochloride (Phenergan) not to be used in children under 6. www.tga.gov.au/news/safety-updates/promethazine-hydrochloride-phenergan-not-be-used-children-under-6

  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application.

- As of 10 December 2025, there were 0 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain alimemazine as an active ingredient.
- Alimemazine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies alimemazine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
alimemazine	C	Allergy and Immune System	Antihistamines	
trimeprazine (alimemazine)	C	Allergy and Immune System	Antihistamines	
Category C – Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to alimemazine to be included on the labelling:

Substance	Conditions	Required statements
Alimemazine (trimeprazine) Entry 1 of 2	In oral medicines that are NOT indicated for cough cold or flu, which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Alimemazine (trimeprazine) Entry 2 of 2	When used as active ingredients in preparations for topical use	This product may make your skin more sensitive to sunlight and other sources of UV light. Sun exposure should be limited by using a sunscreen and by wearing

		protective clothing. Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use. If you have sensitive skin, test this product on a small area of skin before applying it to a large area. Not recommended for use on children and infants.
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. - (for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Triprolidine when NOT separately specified in this table		(for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

- As of 10 December 2025, there were 37 reports of adverse events for products containing alimemazine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 25 reports where alimemazine was the single suspected medicine. There were no reports of death associated with alimemazine use.
- As of 10 December 2025, there were no products containing alimemazine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009-19 no adverse events for humans or animals were recorded for alimemazine in the APVMA Adverse Experience Reporting Program database.
- Alimemazine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Brompheniramine

- According to the TGA Ingredient Database, brompheniramine is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 12 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain brompheniramine as an active ingredient. These are all non-prescription medicines.
- Brompheniramine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies brompheniramine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Brompheniramine	A	Allergy and Immune System	Antihistamines	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to brompheniramine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do

Pheniramine Promethazine Triprolidine when NOT separately specified in this table		not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 3 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: • which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines	In oral preparations indicated for COUGH, COLD OR FLU:	This medication may cause drowsiness.

(Entry 4 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	• which ONLY include dosage instructions for CHILDREN aged between ‘x’ and ‘y’ years (where ‘x’ must not be less than 6 and ‘y’ must not be more than 11)	Do not give to children under ‘x’ years of age. and (if ‘x’ < 12) - Do not give to children between ‘x’ and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Brompheniramine (Entry 1 of 4)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Brompheniramine (Entry 2 of 4)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and ‘y’ years (where 'x' must not be less than 2, and ‘y’ must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under ‘x’ years of age. Do not give to children between 'x' and ‘y’ years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Brompheniramine (Entry 3 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from ‘x’	either - This medication may cause drowsiness. If affected do not drive a vehicle

	years (where 'x' must not be less than 6)	or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Brompheniramine (Entry 4 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

- As of 10 December 2025, there were 88 reports of adverse events for products containing brompheniramine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 83 reports where brompheniramine was the single suspected medicine. There were no reports of death associated with brompheniramine use.
- As of 10 December 2025, there were no products containing brompheniramine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Brompheniramine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Chlorphenamine (Chlorpheniramine)

- According to the TGA Ingredient Database, chlorphenamine is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 106 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain chlorphenamine as an active ingredient. Six are prescription medicines and 97 are non-prescription medicines.

- Chlorphenamine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies chlorphenamine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Chlorphenamine	A	Allergy and Immune System	Antihistamines	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to chlorphenamine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

when NOT separately specified in this table		
Antihistamines (Entry 3 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 4 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Chlorphenamine (Entry 1 of 4)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do

		not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Chlorphenamine (Entry 2 of 4)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Chlorphenamine (Entry 3 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Chlorphenamine (Entry 4 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage	This medication may cause drowsiness.

	instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

- As of 10 December 2025, there were 326 reports of adverse events for products containing chlorphenamine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 259 reports where chlorphenamine was the single suspected medicine. There were 11 reports of death associated with chlorphenamine use.
- As of 10 December 2025, there was one product containing chlorphenamine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009-19 no adverse events for humans or animals were recorded for chlorphenamine in the APVMA Adverse Experience Reporting Program database.
- Chlorphenamine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Dexchlorpheniramine (Dexchlorphenamine)

- According to the TGA Ingredient Database, dexchlorpheniramine is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 13 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain dexchlorpheniramine as an active ingredient. These are all non-prescription medicines.
- Dexchlorpheniramine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies dexchlorpheniramine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Dexchlorpheniramine	A	Allergy and Immune System	Antihistamines	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to dexchlorpheniramine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including:	In oral medicines that include dosage instructions for adults and children aged from 'x'	either - This medication may cause drowsiness. If affected do not drive a vehicle

Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	years (where 'x' must not be less than 2) when NOT separately specified in this table	or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 3 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age,

		except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 4 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between ‘x’ and ‘y’ years (where ‘x’ must not be less than 6 and ‘y’ must not be more than 11)	This medication may cause drowsiness. Do not give to children under ‘x’ years of age. and (if ‘x’ < 12) - Do not give to children between ‘x’ and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Dexchlorpheniramine (Entry 1 of 4)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Dexchlorpheniramine (Entry 2 of 4)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and ‘y’ years (where 'x' must	This medication may cause drowsiness.

	not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Dexchlorpheniramine (Entry 3 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Dexchlorpheniramine (Entry 4 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not b more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

- As of 10 December 2025, there were 220 reports of adverse events for products containing dexchlorpheniramine as an active ingredient on the Database of Adverse Event Notifications

(DAEN), with 174 reports where dexchlorpheniramine was the single suspected medicine. There were no reports of death associated with dexchlorpheniramine use.

- As of 10 December 2025, there were no products containing dexchlorpheniramine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Dexchlorpheniramine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Diphenhydramine

- According to the TGA Ingredient Database, diphenhydramine is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 19 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain diphenhydramine is as an active ingredient. Of these, 18 are non-prescription medicines.
- Diphenhydramine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies diphenhydramine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Diphenhydramine	A	Allergy and Immune System	Antihistamines	
Diphenhydramine	A	Central Nervous System	Antiemetics, antinauseants	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to diphenhydramine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12)

		- Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 3 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 4 of 5) including:	In oral preparations indicated for COUGH, COLD OR FLU:	This medication may cause drowsiness.

Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 5 of 5) including: Diphenhydramine Doxylamine Promethazine	In oral medicines indicated for SHORT TERM USE IN INSOMNIA: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) (Note: Antihistamine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Antihistamines (Entry 2 of 5))	This product should be taken on medical or pharmacist advice. Do not give to children under 'x' years of age. If breastfeeding, consult a doctor or pharmacist before use. Do not take this medicine for more than a few days. This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.
Diphenhydramine (Entry 1 of 5)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12)

		- Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Diphenhydramine (Entry 2 of 5)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Diphenhydramine (Entry 3 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Diphenhydramine (Entry 4 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12)

	instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	- Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Diphenhydramine (Entry 5 of 5)	In oral medicines indicated for SHORT TERM USE IN INSOMNIA: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) (Note: Diphenhydramine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Diphenhydramine (Entry 2 of 5))	This product should be taken on medical or pharmacist advice. Do not give to children under 'x' years of age. If breastfeeding, consult a doctor or pharmacist before use. Do not take this medicine for more than a few days. This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.

- As of 10 December 2025, there were 116 reports of adverse events for products containing diphenhydramine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 55 reports where diphenhydramine was the single suspected medicine. There were 6 reports of death associated with diphenhydramine use.
- As of 10 December 2025, there was one product containing diphenhydramine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009–19 no adverse events for humans or animals were recorded for diphenhydramine in the APVMA Adverse Experience Reporting Program database.
- Diphenhydramine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Doxylamine

- According to the TGA Ingredient Database, doxylamine is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 39 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain doxylamine as an active ingredient, including 10 prescription medicines and 29 non-prescription medicines.
- Doxylamine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies doxylamine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Doxylamine	A	Allergy and Immune System	Antihistamines	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to doxylamine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a

Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table		doctor, pharmacist or nurse practitioner. (for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 3 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 4 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a

Pheniramine Promethazine Triprolidine when NOT separately specified in this table		doctor, pharmacist or nurse practitioner. (for promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 5 of 5) including: Diphenhydramine Doxylamine Promethazine	In oral medicines indicated for SHORT TERM USE IN INSOMNIA: which include dosage instructions for adults and children aged from ‘x’ years (where ‘x’ must not be less than 2) (Note: Antihistamine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to ‘Antihistamines (Entry 2 of 5))	This product should be taken on medical or pharmacist advice. Do not give to children under ‘x’ years of age. If breastfeeding, consult a doctor or pharmacist before use. (for promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use. Do not take this medicine for more than a few days. This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.
Doxylamine (Entry 1 of 5)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12)

		- Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Doxylamine (Entry 2 of 5)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and ‘y’ years (where 'x' must not be less than 2, and ‘y’ must not be more than 11) en NOT separately ecified in this table	This medication may cause drowsiness. Do not give to children under ‘x’ years of age. Do not give to children between 'x' and ‘y’ years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Doxylamine (Entry 3 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from ‘x’ years (where ‘x’ must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under ‘x’ years of age. and (if ‘x’ < 12) - Do not give to children between ‘x’ and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Doxylamine (Entry 4 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between ‘x’ and ‘y’ years (where ‘x’ must not be less than 6 and ‘y’ must not be	This medication may cause drowsiness. Do not give to children under ‘x’ years of age. and (if ‘x’ < 12)

	more than 11)	- Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Doxylamine (Entry 5 of 5)	In oral medicines indicated for SHORT TERM USE IN INSOMNIA: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2)	This product should be taken on medical or pharmacist advice. Do not give to children under 'x' years of age. If breastfeeding, consult a doctor or pharmacist before use. Do not take this medicine for more than a few days. This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.

- As of 10 December 2025, there were 311 reports of adverse events for products containing doxylamine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 138 reports where doxylamine was the single suspected medicine. There were 47 reports of deaths associated with doxylamine use.
- As of 10 December 2025, there were no products containing doxylamine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Doxylamine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Pheniramine

- According to the TGA Ingredient Database, pheniramine is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 2 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain pheniramine as an active ingredient. These are all non-prescription medicines.
- Pheniramine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies pheniramine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Pheniramine		Allergy and Immune System	tihistamines	

Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to pheniramine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines	In oral preparations indicated	Either

(Entry 3 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	- This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines (Entry 4 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Pheniramine (Entry 1 of 4)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or

		- This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Pheniramine (Entry 2 of 4)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Pheniramine (Entry 3 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age,

		except on the advice of a doctor, pharmacist or nurse practitioner.
Pheniramine (Entry 4 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

- As of 10 December 2025, there were 409 reports of adverse events for products containing pheniramine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 334 reports where pheniramine was the single suspected medicine. There were 0 reports of death associated with pheniramine use.
- As of 10 December 2025, there were no products containing pheniramine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Pheniramine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Promethazine

- According to the TGA Ingredient Database, promethazine is available for use as follows:
  - As an active ingredient in: Biologicals, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 40 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain promethazine as an active ingredient, including one prescription medicine and 39 non-prescription medicines.
- Promethazine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies promethazine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Promethazine	C	Allergy and Immune System	Antihistamines	
Promethazine	C	Central Nervous System	Antiemetics, antinauseants	Phenothiazines
Category C – Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible. Accompanying texts should be consulted for further details.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to promethazine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Antihistamines (Entry 3 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicate for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 4 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicate for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Antihistamines (Entry 5 of 5) including: Diphenhydramine Doxylamine Promethazine	In oral medicines indicated for SHORT TERM USE IN INSOMNIA: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) (Note: Antihistamine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Antihistamines (Entry 2 of 5))	This product should be taken on medical or pharmacist advice. Do not give to children under 'x' years of age. If breastfeeding, consult a doctor or pharmacist before use. (for promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use. Do not take this medicine for more than a few days. This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.
Promethazine (Entry 1 of 5)	In oral medicines that include sage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

		If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Promethazine (Entry 2 of 5)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Promethazine (Entry 3 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Promethazine (Entry 4 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Promethazine (Entry 5 of 5)	In oral medicines indicated for SHORT TERM USE IN INSOMNIA: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) (Note: Diphenhydramine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Diphenhydramine (Entry 2 of 5))	This product should be taken on medical or pharmacist advice. Do not give to children under 'x' years of age. If breastfeeding, consult a doctor or pharmacist before use. Do not take this medicine for more than a few days. This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.

- As of 10 December 2025, there were 845 reports of adverse events for products containing promethazine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 316 reports where promethazine was the single suspected medicine. There were 78 reports of death associated with promethazine use.
- As of 10 December 2025, there was one product containing promethazine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In 2009–19 no adverse events for humans or animals were recorded for promethazine in the APVMA Adverse Experience Reporting Program database.
- Promethazine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Triprolidine

- According to the TGA Ingredient Database, triprolidine is available for use as follows:

  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application

- As of 10 December 2025, there were 3 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain triprolidine as an active ingredient. These are all non-prescription medicines.
- Triprolidine is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies triprolidine as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Triprolidine	A	Allergy and Immune System	Antihistamines	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.				

- The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 requires the following warning statements pertaining to triprolidine to be included on the labelling:

Substance	Conditions	Required statements
Antihistamines (Entry 1 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Antihistamines (Entry 2 of 5) including: Alimemazine (trimeprazine) Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under 'x' years of age. Do not give to children between 'x' and 'y' years of age, except on the advice of a doctor, pharmacist or nurse practitioner. (for alimemazine and promethazine only) If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
Antihistamines (Entry 3 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner
Antihistamines (Entry 4 of 5) including: Brompheniramine Chlorphenamine Dexchlorpheniramine Diphenhydramine	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12)

Doxylamine Pheniramine Promethazine Triprolidine when NOT separately specified in this table	than 6 and ‘y’ must not be more than 11)	- Do not give to children between ‘x’ and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Triprolidine (Entry 1 of 4)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	Either - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Triprolidine (Entry 2 of 4)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and ‘y’ years (where 'x' must not be less than 2, and ‘y’ must not be more than 11) when NOT separately specified in this table	This medication may cause drowsiness. Do not give to children under ‘x’ years of age. Do not give to children between 'x' and ‘y’ years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Triprolidine (Entry 3 of 4)	In oral preparations indicated for COUGH, COLD OR FLU:	either - This medication may cause drowsiness. If affected do not drive a vehicle

	which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	or operate machinery. Avoid alcohol. Or - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Triprolidine (Entry 4 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: which ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 6 and 'y' must not be more than 11)	This medication may cause drowsiness. Do not give to children under 'x' years of age. and (if 'x' < 12) - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

- As of 10 December 2025, there were 62 reports of adverse events for products containing triprolidine as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 40 reports where triprolidine was the single suspected medicine. There were no reports of death associated with triprolidine use.
- As of 10 December 2025, there were no products containing triprolidine as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Triprolidine is not included on the Australian Inventory of Industrial Chemicals (Inventory).

Dimenhydrinate

- According to the TGA Ingredient Database, dimenhydrinate is available for use as follows:
  - As an active ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines
  - As an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - Not available as an Equivalent Ingredient in any application
- As of 10 December 2025, there were 19 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain dimenhydrinate as an active ingredient, including 3 are prescription medicines and 13 are non-prescription medicines.

- Dimenhydrinate is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies dimenhydrinate as:

Drug name	Category	Classification Level 1	Classification Level 2	Classification Level 3
Dimenhydrinate	A	Central Nervous System	Antiemetics, antinauseants	
Category A – Drugs which have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the foetus having been observed.				

- Dimenhydrinate is not listed in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 10 December 2025, there were 169 reports of adverse events for products containing dimenhydrinate as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 164 reports where dimenhydrinate was the single suspected medicine. There were no reports of death associated with dimenhydrinate use.
- As of 10 December 2025, there were no products containing dimenhydrinate as an active scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Dimenhydrinate is not included by Australian Industrial Chemicals Introduction Scheme (AICIS) on the Australian Inventory of Industrial Chemicals (Inventory).

International regulations

Alimemazine (Trimeprazine)

- The Health Canada Drug Product Database lists 3 marketed entries containing trimeprazine tartrate: one veterinary product classified as a non-prescription drug and 2 human products classified as prescription medications.
- The New Zealand Medsafe Medicines Classification Database lists alimemazine under the name trimeprazine.
  - Trimeprazine is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults or children over 2 years of age other than in medicines used for the treatment of insomnia, and for oral use for the treatment of insomnia when sold in the manufacturer's original pack containing not more than 10 dosage units.
  - It is classified as Pharmacy Only for oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active ingredients, either when in the bedtime dose of a day/night pack containing trimeprazine or when at least one of the other therapeutically active ingredients is a sympathomimetic decongestant.
- According to the FDA Approved Drug Products Database (Drugs@FDA), no trimeprazine products are currently marketed. All previously listed oral syrup formulations and other dosage forms containing trimeprazine tartrate have been discontinued.
- The European Commission database for information on cosmetic substances and ingredients does not contain any listings for alimemazine (trimeprazine).

Brompheniramine

- There are currently no marketed products on the Health Canada Drug Product Database.

- The New Zealand Medsafe Medicines Classification Database lists brompheniramine with the following classifications:
  - Prescription: Applies except when specified elsewhere in the schedule.
  - Restricted: For oral use in medicines for adults or children over 2 years of age other than in medicines used for sedation or the treatment of insomnia. For oral use for the treatment of insomnia in adults and children 12 years of age and older when sold in the manufacturer's original pack containing not more than 10 dosage units.
  - For oral use for sedation in adults only when sold in the manufacturer's original pack.
  - Pharmacy Only: For oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active ingredients, either when in the bedtime dose of a day/night pack containing brompheniramine or when at least one of the other therapeutically active ingredients is a sympathomimetic decongestant.
- According to the FDA Approved Drug Products Database (Drugs@FDA), 9 combination oral syrup products containing brompheniramine with dextromethorphan and pseudoephedrine are currently listed as approved, while no single-ingredient oral formulations are currently marketed.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations lists 9 prescription-only brompheniramine combination medicines currently available (oral syrup formulations with dextromethorphan and pseudoephedrine). All previously marketed oral formulations containing brompheniramine as a single active ingredient, including syrups, tablets, and capsules, have been discontinued.
- There are 2 listings for brompheniramine in the European Commission cosmetic substances and ingredients database: one for brompheniramine hydrogen maleate and one for brompheniramine and its salts.

Chlorphenamine

- There are no listings on the Health Canada Drug Product Database for chlorphenamine.
- There are no listings on the New Zealand Medsafe Medicines Classification Database for chlorphenamine.
- According to the FDA Approved Drug Products Database (Drugs@FDA), there are no products containing chlorpheniramine is currently available
- The European Commission database for information on cosmetic substances and ingredients does not contain any listings for chlorphenamine.

Dexchlorpheniramine

- There are currently no marketed products for dexchlorpheniramine on the Health Canada Drug Product Database.
- The New Zealand Medsafe Medicines Classification Database lists dexchlorpheniramine with the following classifications:
  - Dexchlorpheniramine is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults or children over 2 years of age other than in medicines used for sedation or the treatment of insomnia; for oral use for the treatment of insomnia in adults and children 12 years of age and older when sold in the manufacturer's original pack containing not more than 10 dosage units; and for oral use for sedation in adults only when sold in the manufacturer's original pack.
  - It is classified as Pharmacy Only for oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active

ingredients, either when in the bedtime dose of a day/night pack containing dexchlorpheniramine or when at least one of the other therapeutically active ingredients is a sympathomimetic decongestant.

- According to the FDA Approved Drug Products Database (Drugs@FDA), one prescription syrup product containing dexchlorpheniramine is currently available.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations lists one prescription-only dexchlorpheniramine medicine currently available (oral syrup formulation). All previously marketed oral tablet and syrup formulations have been discontinued.
- The European Commission database for information on cosmetic substances and ingredients does not contain any listings for dexchlorpheniramine.

Diphenhydramine

- The Health Canada Drug Product Database lists 86 marketed entries containing diphenhydramine with 80 products are classified as non- prescription drugs.
- The New Zealand Medsafe Medicines Classification Database lists diphenhydramine with the following classifications:
  - Diphenhydramine is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults or children over 2 years of age other than in medicines used for sedation or the treatment of insomnia; for oral use for the treatment of insomnia in adults and children 12 years of age and older when sold in the manufacturer's original pack containing not more than 10 dosage units; and for oral use for sedation in adults only when sold in the manufacturer's original pack.
  - Classified as Pharmacy Only for oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active ingredients. This applies either when in the bedtime dose of a day/night pack containing diphenhydramine or when at least one of the other active ingredients is a sympathomimetic decongestant. It also applies for oral use when sold in the manufacturer's original pack of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 6 years of age. This excludes packs sold at a transport terminal or aboard a ship or aircraft for adults and children over 6 years of age.
- According to the FDA Approved Drug Products Database (Drugs@FDA), 8 combination oral products containing diphenhydramine with analgesics such as ibuprofen or naproxen are currently available over the counter. In addition, several injectable formulations are available as prescription medications. No single-ingredient oral formulations of diphenhydramine remain marketed.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations lists 10 prescription-only diphenhydramine medicines currently available (oral elixir and injectable formulations). In addition, 14 over-the-counter combination products containing diphenhydramine with ibuprofen or naproxen remain marketed. All previously marketed oral capsule formulations, numerous elixir and syrup products, and several injectable strengths have been discontinued.
- The European Commission database for information on cosmetic substances and ingredients contains 5 listings for diphenhydramine and its salts.

Doxylamine

- The Health Canada Drug Product Database lists 23 marketed entries containing doxylamine and all of these are classified as non-prescription drugs.
- The New Zealand Medsafe Medicines Classification Database lists doxylamine with the following classifications:

  - Doxylamine is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults or children over 2 years of age other than in medicines used for sedation or the treatment of insomnia; for oral use for the treatment of insomnia in adults and children 12 years of age and older when sold in the manufacturer's original pack containing not more than 10 dosage units; and for oral use for sedation in adults only when sold in the manufacturer's original pack.
  - It is classified as Pharmacy Only for oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active ingredients, either when in the bedtime dose of a day/night pack containing doxylamine or when at least one of the other therapeutically active ingredients is a sympathomimetic decongestant.

- According to the FDA Approved Drug Products Database (Drugs@FDA), one single-ingredient product containing doxylamine succinate (Unisom) is currently available over the counter, and 6 combination products containing doxylamine and pyridoxine hydrochloride are available as prescription medications.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations lists 7 prescription-only doxylamine-containing medicines currently available (oral tablet formulations), all combining doxylamine succinate with pyridoxine hydrochloride. In addition, 3 over-the-counter doxylamine succinate oral tablet formulations remain marketed. All previously marketed capsule formulations, and several tablet strengths have been discontinued.
- The European Commission database for information on cosmetic substances and ingredients contains 2 listings for doxylamine, available as the base substance and its salts.

Pheniramine

- The Health Canada Drug Product Database lists one marketed entry containing pheniramine which is classified as non-prescription drug.
- The New Zealand Medsafe Medicines Classification Database lists pheniramine with the following classifications:
  - Pheniramine is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults or children over 2 years of age other than in medicines used for sedation or the treatment of insomnia; for oral use for the treatment of insomnia in adults and children 12 years of age and older when sold in the manufacturer's original pack containing not more than 10 dosage units; and for oral use for sedation in adults only when sold in the manufacturer's original pack.
  - It is classified as Pharmacy Only for ophthalmic use except when sold in practice by an optometrist registered with the Optometrists and Dispensing Opticians Board; and for oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active ingredients, either when in the bedtime dose of a Pharmacy day/night pack containing pheniramine or when at least one of the other therapeutically active ingredients is a sympathomimetic decongestant.
- According to the FDA Approved Drug Products Database (Drugs@FDA) there are no listings for pheniramine available.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations lists multiple over-the-counter ophthalmic solutions containing pheniramine maleate (in combination with naphazoline hydrochloride) that are currently available. No oral formulations of pheniramine are marketed; all previously listed oral products have been discontinued.

- The European Commission database for information on cosmetic substances and ingredients does not contain any listings for pheniramine.

Promethazine

- The Health Canada Drug Product Database lists one marketed entry containing promethazine which is classified as non-prescription drug.
- The New Zealand Medsafe Medicines Classification Database lists promethazine with the following classifications:
  - Promethazine is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults or children over 2 years of age other than in medicines used for sedation or the treatment of insomnia; for oral use for the treatment of insomnia in adults and children 12 years of age and older when sold in the manufacturer's original pack containing not more than 10 dosage units; and for oral use for sedation in adults only when sold in the manufacturer's original pack.
  - It is classified as Pharmacy Only for oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active ingredients, either when in the bedtime dose of a day/night pack containing promethazine or when at least one of the other therapeutically active ingredients is a sympathomimetic decongestant; and for oral use when sold in the manufacturer's original pack of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults and children over 6 years of age, except when sold at a transport terminal or aboard a ship or aircraft for adults and children over 6 years of age.
- According to the FDA Approved Drug Products Database (Drugs@FDA), 9 single-ingredient products containing promethazine hydrochloride are currently available as prescription medications in various forms (tablets, syrups, suppositories, and injectables). In addition, 8 combination products containing promethazine with codeine, dextromethorphan, or phenylephrine are also available as prescription medications.
- The United States Food and Drug Administration's Orange Book*:* Approved Drug Products with Therapeutic Equivalence Evaluations lists multiple prescription-only medicines containing promethazine that are currently available in various forms, including oral tablets, oral syrups, rectal suppositories, and injectable formulations. Numerous other previously marketed products, including additional oral and injectable formulations, have been discontinued.
- The European Commission database for information on cosmetic substances and ingredients does not contain any listings for promethazine.

Triprolidine

- The Health Canada Drug Product Database lists 2 marketed entries containing triprolidine which are classified as narcotics.
- The New Zealand Medsafe Medicines Classification Database lists triprolidine with the following classifications:
  - Triprolidine is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults or children over 2 years of age, except when specified elsewhere in the schedule.
  - It is classified as Pharmacy Only for oral use in medicines for adults and children over 6 years of age when combined in the same container with one or more other therapeutically active ingredients, either when in the bedtime dose of a day/night pack containing triprolidine or when at least one of the other therapeutically active ingredients is a sympathomimetic decongestant.

- According to the FDA Approved Drug Products Database (Drugs@FDA), one combination product containing triprolidine (with pseudoephedrine and codeine) is currently available as a prescription medication. All other single-ingredient and combination products containing triprolidine have been discontinued.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations lists one prescription-only medicine containing triprolidine (in combination with pseudoephedrine and codeine) that is currently available as an oral syrup. All other single-ingredient and combination products, including tablets, capsules, and syrups, have been discontinued.
- The European Commission database for information on cosmetic substances and ingredients does not contain any listings for triprolidine.

Dimenhydrinate

- The Health Canada Drug Product Database lists 21 marketed entries containing dimenhydrinate of which 15 products are classified as non- prescription drugs.
- The New Zealand Medsafe Medicines Classification Database lists dimenhydrinate with the following classifications:
  - Dimenhydrinate is classified as Prescription except when specified elsewhere in the schedule.
  - It is Restricted for oral use in medicines for adults and children over 2 years of age, except when specified elsewhere in the schedule.
  - It is classified as Pharmacy Only for oral use in a sealed container of not more than 10 tablets or capsules for the prevention or treatment of motion sickness in adults or children over 2 years of age, except when sold at a transport terminal or aboard a ship or aircraft.
- According to the FDA Approved Drug Products Database (Drugs@FDA), one injectable formulation containing dimenhydrinate is currently available as a prescription medication. All other oral and injectable products have been discontinued.
- The United States Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations lists one prescription-only dimenhydrinate medicine currently available (injectable formulation). All previously marketed oral tablets, and liquid formulations have been discontinued.
- The European Commission database for information on cosmetic substances and ingredients does not contain any listings for dimenhydrinate.

2 Proposed amendments referred for scheduling advice to ACCS meeting #41

2.1 Oxalic acid

Proposal

The proposal is to amend the current Poison Standard with regards to the oxalic acid Poison (Schedule 6) entry and to create a new Caution (Schedule 5) entry for oxalic acid when in a slow-release solid matrix strip for beehive use containing 10 g or less of oxalic acid.

Under the proposal, the solid matrix strip product will be captured under Schedule 5 with the CAUTION signal heading, rather the POISON signal header.

CAS Number

144-62-7 (oxalic acid)
65153-56-6 (oxalic acid dihydrate)

Alternative names

Ethanedioic acid

Applicant

Australian Pesticides and Veterinary Medicines Authority (APVMA)

Proposed Scheduling

Oxalic acid is currently listed in Schedule 6 of the Poisons Standard as follows:

Schedule 6

OXALIC ACID **except**

(a) in dental care preparations, including mouthwashes, containing 3% or less of soluble salts of oxalic acid; or

(b) its insoluble salts.

It is also included under the entry OXALIC ACID in Appendix E and Appendix F as follows:

Appendix E, Clause 3 – First aid instructions for poisons

Item	Poison	Statement code (and statement)
228	OXALIC ACID	A – For advice, contact a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor (at once). G3 – If swallowed, do NOT induce vomiting. E2 – If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by a Poisons Information Centre (e.g. phone Australia 13 11 26; New Zealand 0800 764 766) or a doctor, or for at least 15 minutes. S1 – If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water.

Appendix F, Clause 4 – Warning statements and general safety directions for poisons – Poisons that must be labelled with warning statements and safety directions

Item	Poison	Warning statement item number (and statement)	Safety direction item number (and statement)
252	OXALIC ACID	2 - Corrosive.	4 – Avoid contact with skin 8 – Avoid breathing dust (or) vapour (or) spray mist.

The applicant's proposed amendments to the Poisons Standard are[11]:

Schedule 6 – Amend Entry

OXALIC ACID **except**

(a) in dental care preparations, including mouthwashes, containing 3% or less of soluble salts of oxalic acid; or

(b) its insoluble salts; or

(c) when included in Schedule 5.

Schedule 5 – New Entry

OXALIC ACID in a slow-release solid matrix strip for beehive use containing 10 g or less of oxalic acid.

No change is proposed in relation to Appendix E and Appendix F.

Background

Oxalic acid is an organic acid that occurs naturally in food (e.g. spinach, rhubarb, coffee, chocolate, tea, etc.). Oxalic acid is also produced endogenously in mammals as an end-product of the metabolism of glycine, glycolate and ascorbic acid.

Oxalic acid dihydrate (CAS No. 65153-56-6) is a proposed new veterinary active constituent which is captured under the oxalic acid entry (Schedule 6) in the Poisons Standard. It is a component of a proposed Slow-Release Oxalic Acid Strip product for Beehives, which is currently being considered by the APVMA for registration as a parasiticide for the control of varroa mites in beehives.

Currently, oxalic acid is listed as a Poison (Schedule 6) in the latest Poisons Standard, with exceptions for dental care preparations and insoluble salts. Under existing scheduling, the product would require a POISON signal header on its label.

The application seeks an amendment to include oxalic acid in Schedule 5 when in slow-release strips for beehive use, citing lower risk due to the formulation type and limited user exposure.

Summary of applicant's reasons for the proposal

In Australia, oxalic acid containing products are classified as Poison (Schedule 6) except for dental care preparations below a certain concentration, and insoluble salts. Oxalic acid dihydrate is a new veterinary active constituent in Australia. It is proposed for use in a slow-release oxalic acid strip formulation product (10 g per strip) to control varroa mites in beehives. It is intended for professional application and for the strips to be applied once per year and removed after 42 days.

[11] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

As the applicant did not submit an acute toxicity data package for the product, the acute toxicity of the formulated product was estimated based on the hazard profile of each constituent, in order to establish the safety directions and personal protective equipment (PPE) requirements for the product. The proposed product is estimated to have low oral, dermal and inhalation toxicity. The substance is estimated to be severely irritating, corrosive to the skin and eyes, and is not likely to be a skin sensitiser.

To address relevant toxicity endpoints, the applicant provided several assessment reports or decision documents from other regulators, including the IMAP assessments from the Australian Industrial Chemicals Introduction Scheme (AICIS, formerly NICNAS), the regulatory decision document from Canada's PMRA, the evaluation report from the European Agency for the Evaluation of Medicinal Products (EMA), several reports/documents from the US EPA and a number of other references from the open literature.

The APVMA undertook a quantitative exposure and risk assessment for workers applying and re-handling the product. Workers applying the product may be exposed repeatedly by the dermal route. Dermal exposure may also occur during post-application activities e.g. hive maintenance or when removing strips after 42 days. The APVMA has undertaken a user risk assessment, culminating in appropriate first aid instructions, safety directions, restraints and re-handling statement to be included on the proposed label.

Reasoning provided for the Schedule 5 consideration of the proposed product is that the strips are dry when handled resulting in limited worker exposure. However, insufficient information was provided to conclude if the proposed product meets Schedule 5 criteria without users wearing PPE (gloves, overalls) and handling no more than 400 strips per day.

After consideration of the toxicological profile and likely human exposure associated with the use of oxalic acid dihydrate in the proposed product - Slow-Release Oxalic Acid Strips for Beehives, the APVMA concluded that the human health risks are acceptable when used in accordance with the directions for use (DFU) and adhering to the recommended safety directions, restraints and re-handling statements.

Key uses / expected use

For beehive use and professional use only.

Australian regulations

- According to the TGA Ingredient Database, oxalic acid is:
  - available for use as an active ingredient in: Biologicals, Export Only, Listed Medicines, Over the Counter, and Prescription Medicines.
  - available for use in Listed Medicines as an active Homoeopathic Ingredient only up to a total concentration of 10 mg/kg or 10 mg/L or 0.001%.
  - available for use as an Excipient Ingredient in: Biologicals, Devices, Prescription Medicines
  - not available as an Equivalent Ingredient in any application.
- As of 8 December 2025, there were no medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain oxalic acid as an active ingredient.
- According to the Therapeutic Goods (Permissible Ingredients) Determination No. 4 of 2025, oxalic acid is permitted to be included in listed medicines as follows.

Item	Ingredient name	Purpose	Specific requirements
3633	Oxalic acid	H	Only for use as an active homoeopathic ingredient. The total concentration of oxalic acid in the medicine must not be more than 10 mg/kg or 10 mg/L or 0.001%.

H = homoeopathic preparation ingredient meaning an ingredient that is a constituent of a homoeopathic preparation

- The TGA prescribing medicines in pregnancy database does not include oxalic acid.
- There are no warning statements pertaining to oxalic acid in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 8 December 2025, there were no reports of adverse events for products containing oxalic acid as an active ingredient on the Database of Adverse Event Notifications (DAEN).
- As of 8 December 2025, there were no products containing oxalic acid as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- In Agricultural and Veterinary Permits Search database, Api-Bioxal, a product containing oxalic acid, used to treat Varroa mite infestations in *Apis* species within the beekeeping industry. This is currently operating under an emergent permit (valid from 11 November 2024 to 30 September 2028) issued by the APVMA to NSW Department of Primary Industries (DPI).
- In 2009–2019, no adverse experiences were recorded for oxalic acid in the APVMA Adverse Experience Reporting Program database.
- Oxalic acid is listed on the Australian Inventory of Industrial Chemicals and a Human Health Tier II Assessment of Oxalic acid was published by the National Industrial Chemicals Notification and Assessment Scheme (now Australian Industrial Chemicals Introduction Scheme) in 2014.

International regulations

- In the United States Environmental Protection Agency's Office of Pesticide Programs Database oxalic acid is registered, and its pesticide type is listed as conventional chemical pesticide.
- In Europe, oxalic acid is listed in European Commission database for information on cosmetic substances and ingredients database (CosIng) as a chelating substance.
- According to European Chemical Agency (ECHA), oxalic acid is registered under the REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) Regulation and is manufactured in and/or imported to the European Economic Area. The substance has widespread use including consumer products for coating, polishes, waxes, washing and cleaning. According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is harmful if swallowed and is harmful in contact with skin. Oxalic acid is also identified as a substance that can cause serious eye damage.
- According to the European Medicines Agency, 73 veterinary medicines (72 authorised, 1 not authorised) containing oxalic acid or oxalic acid dihydrate for beehive use.
- In the EU and ASEAN countries and New Zealand, the use of oxalic acid in hair products is restricted to professional use and at a maximum concentration of 5% through listing in the following:
  - ASEAN Cosmetic Directive Annex III – Part 1 (List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down);
  - EU Regulation (EC) No 1223/2009 Annex III (List of substances which cosmetic products must not contain except subject to the restrictions laid down).
- In New Zealand, oxalic acid is not individually approved but may be used under an appropriate group standard with similar GHS classification and toxicity data (New Zealand Inventory of Chemicals (NZIoC) database). New Zealand has also placed restrictions on oxalic acid in hair care products similar to EU and the ASEAN countries by placing it in the New Zealand Cosmetic

Products Group Standard (Schedule 5—Table 1; Components cosmetic products must not contain except subject to the restrictions and conditions laid down).

- As of 8 December 2025, oxalic acid is not listed in European Commission Comitology Register, New Zealand Medicines and Medical Devices Safety Authority (MedSafe), The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, and United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA).
- As of 8 December 2025, 7 cancelled post-market homeopathic products containing oxalic acid are listed in the Health Canada Drug Product Database.

2.2 Flufenoximacil

Proposal

The applicant has proposed to amend the current Poisons Standard in relation to flufenoximacil to create a new Caution (Schedule 5) entry. The substance is intended for use as a professional agricultural herbicide. Flufenoximacil is not included in the current Poisons Standard.

CAS Number

2759011-88-4

Alternative names

Methyl (2R)-2-[(E)-[2-chloro-4-fluoro-5-[3-methyl-2,6-dioxo-4-(trifluoromethyl)pyrimidin-1-yl]phenyl]methylideneamino]oxypropanoate

Methyl (2R)-2-[[(E)-[[2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2H)-pyrimidinyl]-4-fluorophenyl]methylene]amino]oxy]propanoate

Applicant

Private applicant

Proposed Scheduling

Schedule 5 – New Entry

FLUFENOXIMACIL

Index - New Entry

FLUFENOXIMACIL

Schedule 5

Background

Flufenoximacil is a non-selective herbicide, effective against a wide range of weeds, not targeting specific crop species. Flufenoximacil will not be available for 'home garden' or other domestic use.

Flufenoximacil inhibits protoporphyrinogen-oxidase (PPO) in plant chloroplasts and interferes with haemoglobin synthesis in mammals. It provides broad-spectrum weed control and improved performance in plantations, orchards, tea gardens, row crops, and non-cultivated areas, including weeds that are resistant to glyphosate and glufosinate.

The proposed herbicide product that will contain the active constituent flufenoximacil will be used for pre-sowing application to control weeds and grasses for crops such as pulses and cereals.

Flufenoximacil is intended for professional agricultural use only. The user will be expected to use standard personal protective equipment in line with the associated APVMA label.

Summary of applicant's reasons for the proposal

Australian farmers have traditionally relied on glyphosate and paraquat to control difficult weeds such as ryegrass. However, glyphosate resistance is now widespread, and the lack of alternatives has led to increased use of paraquat. This situation has created an urgent demand for a new, stand-alone herbicide with a different mode of action to effectively manage ryegrass and other major weeds. Flufenoximacil's toxicity profile is more favourable to that of paraquat thereby providing for much improved user and environmental outcomes. Flufenoximacil provides Australian growers with a much-needed option to circumvent growing herbicide resistance.

Flufenoximacil acts similarly to approved herbicides like oxyfluorfen, butafenacil, tiafenacil, and saflufenacil, all of which are included in the Poisons Standard. Oxyfluorfen, butafenacil, and tiafenacil are included in Appendix B (Substances considered not to require control by scheduling) for agricultural use. Saflufenacil is included in Schedule 5 (Caution) when dispersed in water dispersible granules or a water-based suspension concentrate or Schedule 7 (Dangerous poisons) when in it is in any other form. Butafenacil, oxyfluorfen and tiafenacil have similar acute toxicity profiles to saflufenacil, but are not developmental toxicants. Saflufenacil is in Schedule 5 and 7, based on developmental toxicity seen in rats (but not in rabbits). The other hazards observed for saflufenacil were slight skin and minimal eye irritation in rabbits.

The applicant has submitted a package of research papers of animal test studies on both flufenoximacil and the intended products to demonstrate that they meet the criteria for scheduling as Caution (Schedule 5) due to low acute toxicity. The data indicate that flufenoximacil has no significant toxicological effects, such as respiratory sensitisation, mutagenicity, carcinogenicity, or reproductive toxicity. Flufenoximacil is unlikely to cause irreversible toxicity with repeated use. It is shown to be non-corrosive and presents minimal acute oral, dermal, and inhalation hazards. The substance is not a skin irritant nor sensitiser, and eye irritation is slight. Developmental toxicity studies were carried out in rats and rabbits. Minor developmental effects were observed at high doses in rats.

The applicant considers that the likelihood of injury may be mitigated through appropriate packaging and label warnings. Potential harm is anticipated to be further reduced by adequate packaging, appropriate storage, and clear warnings, making this substance appropriate for use by professionals with a low risk of injury.

Key uses / expected use

Agriculture

Australian regulations

- Flufenoximacil has not yet been approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Pending approval, the applicant intents to submit a product application for registration in accordance with the APVMA labelling and packaging requirements.
- Flufenoximacil is not listed by the Australian Industrial Chemicals Introduction Scheme (AICIS) on the Australian Inventory of Industrial Chemicals (Inventory).
- Flufenoximacil is not currently listed on the Australian Register of Therapeutic Goods (ARTG).

International regulations

- Flufenoximacil is not listed in the U.S Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA), Health Canada's Public Registry (PMRA), European Chemicals Agency database (ECHA), European Food Safety Authority (EFSA) or New Zealand Environmental Protection Authority (EPA).

- The Pesticide Properties Database (PPDB) - UK reports that there is very limited information on human toxicity for flufenoximacil, including acute oral, dermal, and inhalation data. The only human-health marker is a threshold of toxicological concern (Cramer Class III—"High"), indicating that the substance has a complex or reactive chemical structure and cannot be presumed safe based on structural features alone.
- Key international standards organisations, such as the World Health Organization (WHO) and Food and Agriculture Organization (FAO) Joint Meetings on Pesticide Residues (JMPR) and Codex Alimentarius, have not yet conducted formal assessments on flufenoximacil. Consequently, no global maximum residue limits (MRLs) have been established.
- In China, Institute for the Control of Agrochemicals, Ministry of Agriculture (ICAMA) has approved flufenoximacil for agricultural use and export-only purposes.[1] However, its application is strictly forbidden in or near nature reserves, including aquatic plant breeding zones, aquaculture regions, and mangrove ecosystems.[12]

[12] https://nyfzx.cn/showPDBI.aspx?id=4048

3 Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS meeting #43

3.1 Methylene Blue

Proposal

The Department of Health, Disability and Ageing has proposed to amend the current Poisons Standard in relation to methylene blue. Under the proposal, all preparations of methylene blue for internal use would be included in Prescription-only medicines (Schedule 4).

CAS Number

61-73-4

Alternative names

3,7-bis(Dimethylamino)phenazathionium chloride

Tetramethylthionine chloride

Proposed Scheduling

Methylene blue is currently listed in Schedule 4 of the Poisons Standard as follows:

Schedule 4

METHYLENE BLUE in preparations for injection.

Schedule 5

METHYLENE BLUE in preparations for veterinary use containing 50% or less of methylene blue.

Schedule 7

METHYLENE BLUE for veterinary use except when included in Schedules 4 or 5.

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METHYLENE BLUE

Schedule 7

Schedule 5

Schedule 4

The proposed amendment to the Schedule 4 entry only is:[13]

Schedule 4 – Amend Entry

METHYLENE BLUE in preparations for ~~injection~~ internal use

Background

Methylene blue is used as a treatment for methemoglobinemia (a rare blood disease) in humans and dogs, as well as malaria, cystitis, shock, cyanide and carbon monoxide poisoning. As a therapeutic

[13] Proposed additions are shown in green underlined font, proposed deletions are shown in red strikethrough font, and text without this formatting represents the current text in the Poisons Standard.

product, it is administered via injection. Liquid and powder (for dilution) preparations are also used as a synthetic dye for staining in dental, laboratory and medical diagnostic settings, a synthetic dye in the textile industry and as a treatment in aquariums for various fish ailments, particularly ich (white spot disease) and fungal infections. There are 7 products registered on the ARTG containing methylene blue for use as an injection in Australia.

Summary of applicant's reasons for the proposal

Whilst intravenous methylene blue is used in professional healthcare settings to treat a variety of indications, use of unscheduled oral preparations has increased over the past 12 months. Oral methylene blue has no approved products for therapeutic use in Australia.

There has been a proliferation of websites which sell methylene blue products for oral use, touting unproven claims and often then marking their packages as "not for therapeutic use" or "not for human consumption". The wellness claims include improved cognitive and anti-aging properties. Oral methylene blue preparations are also being promoted on social media platforms.

Over the past 12 months, there has been a significant increase in personal import referrals to the TGA from the Australian Border Force (ABF) for methylene blue products, particularly oral methylene blue products. State and territory poisons information centres have also seen an increase in adverse events reported over the same period. Reported adverse events associated with methylene blue include nausea, diarrhea, dizziness, discomfort/pain during urination, skin discoloration, and irritability. Methylene blue has also been reported to cause the serious condition serotonin syndrome when interacting with other medicines and also can cause birth defects.[14]

The evidence suggests that methylene blue is not safe as an oral preparation when unscheduled. The increased misuse of methylene blue and observed increase in adverse event reporting is likely linked to the wellness claims that are being made.

However, methylene blue may potentially cause mutagenicity and carcinogenicity, as seen in animal models.[15] It is also reported in literature as posing several risks to human health, including birth defects, and red blood cell destruction.[16,17,18] Methylene blue is contraindicated in many conditions including pregnancy, patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency and patients taking antidepressants or some pain killers.[19]

Therefore, to manage the risks of misuse of oral preparations, it is proposed that all preparations for internal use are scheduled as Prescription-only medicines (Schedule 4).

Key uses / expected use

Medicines, dental, veterinary, agricultural, industrial, laboratory and medical diagnostic use.

[14] Hazekamp, C., Schmitz, Z. & Scoccimarro, A. Methylene Blue–Induced Serotonin Toxicity: Case Files of the Medical Toxicology Fellowship at the New York City Poison Control Center. J. Med. Toxicol. 20, 54–58 (2024). https://doi.org/10.1007/s13181-023-00972-0

[15] National Toxicology Program. Toxicology and carcinogenesis studies of methylene blue trihydrate (Cas No. 7220-79-3) in F344/N rats and B6C3F1 mice (gavage studies). Natl Toxicol Program Tech Rep Ser. 2008 May;(540):1-224.

[16] Sun L, Hu D, Zhang Z, Deng X. Oxidative Degradation of Methylene Blue via PDS-Based Advanced Oxidation Process Using Natural Pyrite. *International Journal of Environmental Research and Public Health*. 2019; 16(23):4773. https://doi.org/10.3390/ijerph16234773

[17] Mulushewa Z, Dinbore WT, Ayele Y. Removal of methylene blue from textile waste water using kaolin and zeolite-x synthesized from Ethiopian kaolin. Environ Anal Health Toxicol. 2021 Mar;36(1):e2021007-0. doi: 10.5620/eaht.2021007. PMID: 33765746; PMCID: PMC8207001.

[18] Contreras M, Grande-Tovar CD, Vallejo W, Chaves-López C. Bio-Removal of Methylene Blue from Aqueous Solution by *Galactomyces geotrichum* KL20A. *Water*. 2019; 11(2):282. https://doi.org/10.3390/w11020282

[19] Richardson SR, O'Malley GF. Glucose-6-Phosphate Dehydrogenase Deficiency. 2022 Sep 26. In: StatPearls [Internet]. Treasure Island (FL): StatPearls

Australian regulations

- According to the TGA Ingredient Database, methylene blue is available for use as an active ingredient in: Biologicals, Export Only, Over the Counter and Prescription Medicines.
- As of 11 December 2025, there were 10 medicines currently active on the Australian Register of Therapeutic Goods (ARTG) that contain methylene blue as an active ingredient. These include 7 registered prescription medicines and 3 export-only medicines.
- Methylene blue is not permitted to be included in listed medicines as it is not included in the Therapeutic Goods (Permissible Ingredients) Determination No.4 of 2025.
- The TGA prescribing medicines in pregnancy database classifies methylene blue as:

Drug name	Category	Safety Statement	Classification Level 1
Methylene blue	D	There have been reports of haemolytic anaemia and hyperbilirubinaemia in neonates exposed to methylene blue in the amniotic cavity.	Blood and Haemopoietic System
Category D – Drugs which have caused, are suspected to have caused or may be expected to cause, an increased incidence of human foetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects. Accompanying texts should be consulted for further details.			

- There are no warning statements pertaining to methylene blue in the Therapeutic Goods (Medicines Advisory Statements) Specification 2021.
- As of 11 December 2025, there were 49 reports of adverse events for products containing methylene blue as an active ingredient on the Database of Adverse Event Notifications (DAEN), with 30 reports where methylene blue was the single suspected medicine. There were 6 reports of deaths associated with methylene blue use.
- As of 11 December 2025, there were 13 products containing methylene blue as an active ingredient/constituent or scheduled substance listed on the Public Chemical Registration Information System Search (PubCRIS).
- Between 2015–2020 there were no adverse experiences recorded for methylene blue in the APVMA Adverse Experience Reporting Program database (AERP).
- Methylene blue is included by Australian Industrial Chemicals Introduction Scheme (AICIS) on the Australian Inventory of Industrial Chemicals (Inventory).

International regulations

- The United States Food and Drug Administration Approved Drug Products Database (Drugs@FDA) includes methylene blue as a prescription only medicine for intravenous use. There are 9 entries containing methylene blue in The Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, all of which are 5 mg/mL intravenous preparations. It is also included on the FDA's Global Substance Registration System (UNII: T42P99266K).
- Methylene blue is not included on the European Commission's General Index of Products and is not included on the European Commission database for information on cosmetic substances and ingredients database.
- The New Zealand Medicines and Medical Devices Safety Authority (MedSafe) allows methylene blue for general sale except for in preparations for injection which are prescription-only.
- In Canada, there are 2 non-prescription products listed in the Canadian (Health Canada) Drug Product Database as currently on the market containing 0.2 mg/mL or 1% methylene blue in liquid

oral preparations. There are also 2 products for injection as 'ethical' scheduled drugs (non-prescription professional use products).[20]

- As an antimicrobial agent used in agriculture, it is listed as an approved active constituent in the United States Environmental Protection Agency's (US EPA) Office of Pesticides Programs. It is registered on the European Chemicals Agency (ECHA) with a corrosive (GHS05) and health hazard (GHS07) classification and is included in Annex III as a substance predicted as likely to meet criteria for category 1A or 1B carcinogenicity, mutagenicity, or reproductive toxicity, or with dispersive or diffuse use(s) where predicted likely to meet any classification criterion for health or environmental hazards, or where there is a nanoform soluble in biological and environmental media.
- The New Zealand Inventory of Chemicals (NZIoC) lists methylene blue as a substance that does not have an individual approval but may be used under an appropriate group standard.
- Methylene blue is not included on the Pesticide Product Information Database of Canada's Pest Management Regulation Agency.

[20] Health Canda Drug product database: Terminology - Canada.ca

How to respond

Submissions must be provided by the closing date of 29 January 2026 through our consultation hub. Any submission about any of the proposals to amend the Poisons Standard will be considered at the next meeting of the Advisory Committee on Medicines Scheduling (ACMS), meeting of the Advisory Committee on Chemicals Scheduling (ACCS), or a joint meeting of these two committees.

What will happen

All public submissions will be published on the TGA website at Public submissions on scheduling matters, unless marked confidential or indicated otherwise in the submission coversheet (see Privacy information).

Following consideration of public submissions received before the closing date and advice from the expert advisory committee/s, decisions on the proposed amendments will be published as interim decisions on the TGA website: Scheduling delegate's interim decisions & invitations for further comment in June 2026.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au