



Therapeutic Goods (Medicines Advisory Statements) Specification 2019

I, Jane Cook, as delegate of the Minister for Health, make the following specification.

Dated 26 February 2019

Jane Cook
First Assistant Secretary
Medicines Regulation Division
Health Products Regulation Group
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Medicines Advisory Statements) Specification 2019*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 March 2019.	1 March 2019

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 3(5A) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

- (a) current Poisons Standard;
- (b) label;
- (c) medicine; and
- (d) therapeutic use.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

dermal use means application to the skin primarily for localised effect.

divided preparation means a preparation manufactured and packed as discrete pre-measured dosage units prior to sale or supply, and includes tablets, capsules, cachets, single dose powders or single dose sachets of powders or granules.

dosage unit means an individual dose of a medicine for therapeutic use and includes a tablet, capsule, cachet, single dose powder or single dose sachet of powders or granules.

essential oils means products obtained from natural raw materials either by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation. It also means:

- (a) oils of equivalent composition derived through synthetic means; or
- (b) compounded oils of equivalent composition comprising a mixture of synthetic and natural components.

external in relation to the use of a medicine means application in the ears, eyes or nose or to a body surface other than in the mouth, rectum, vagina, urethra or other body orifice.

internal use means administration:

- (a) orally, except for topical effect in the mouth; or
- (b) for absorption and the production of a systemic effect,
 - (i) by way of a body orifice other than the mouth; or
 - (ii) parenterally, other than by application to unbroken skin.

main label means:

- (a) where there are two or more labels or two or more portions of a single label – that label or portion of the label where the product name is more or most conspicuously shown; or
- (b) where the product name is equally conspicuous on two or more labels or portions of a label – each such label or portion.

medicine in a prescribed class means medicine included in a class of medicine prescribed by the Regulations for the purposes of paragraph 3(5)(ca) of the Act.

MRDD or **maximum recommended daily dose** means the maximum approved dose per day for a medicine used for its main indication in adults.

Poisons Standard means the current Poisons Standard as in force on the commencement of this instrument.

Regulations means the *Therapeutic Goods Regulations 1990*.

signal heading means the signal word or words relating to a Schedule to the SUSMP in which the substance is included and the purpose for which it is to be used, as shown in the following table:

Schedule	Purpose	Signal words required
2	For any purpose	PHARMACY MEDICINE
3	For any purpose	PHARMACIST ONLY MEDICINE
4	For human use	PRESCRIPTION ONLY MEDICINE
5	For any purpose	CAUTION
6	For any purpose	POISON
7	For any purpose	DANGEROUS POISON
8	For any purpose	CONTROLLED DRUG

SUSMP means the Standard for the Uniform Scheduling of Medicines and Poisons, as set out in Schedule 1 to the Poisons Standard.

topical use means application of a substance for the purpose of producing a localised effect on the surface of the organ or within the tissue to which it is applied.

5 Interpretation

- (1) Unless the contrary intention appears, a reference to a substance in this instrument includes:
 - (a) that substance as prepared from natural sources or artificially; and
 - (b) where the substance is a plant (other than a plant referred to in Schedules 8 or 9 of the SUSMP), that plant or any part of that plant when packed or prepared for therapeutic use; and
 - (c) every salt, active principle or derivative of the substance, including esters and ethers and every salt of such an active principle or derivative; and
 - (d) every alkaloid of the substance and every salt of such an alkaloid; and
 - (e) except where the stereoisomer is defined in the substance name (e.g. dextromethorphan), every stereoisomer of the substance and every salt of such a stereoisomer; and
 - (f) a preparation or admixture containing any proportion of the substancebut does not include:
 - (g) a preparation or product included in Appendix A of the SUSMP; or
 - (h) a substance included in Appendix G of the SUSMP at a concentration not exceeding the concentration specified in column 2 of that Appendix in respect of the substance; or
 - (i) any other substance included in Schedules 1 to 6 to the SUSMP, at a concentration not exceeding 10 mg per litre or 10 mg per kilogram, unless that substance is also included in Schedule 7 or 8 to the SUSMP.
- (2) Unless the contrary intention appears, where a concentration, strength or quantity is specified in this instrument in respect of a substance:
 - (a) if the substance is present as a salt, active principle or derivative (including an ester or ether), the concentration, strength or quantity is calculated as the equivalent amount of the substance that is listed in this instrument; and
 - (b) the expression “one per cent” means:
 - (i) in the case of a liquid preparation, 1 gram of the substance per 100 mL of the preparation; or
 - (ii) in the case of a solid or semi-solid preparation, 1 gram of the substance per 100 grams of the preparation and
 - (iii) any expression of greater or lesser percentages shall have a corresponding meaning; and
 - (c) in the case of codeine, such concentration, strength or quantity is calculated as anhydrous codeine.
- (3) In Schedule 1, the following symbols in column 3 have the following meanings:

Symbol	Meaning
[c]	Statement(s) must be included at the beginning of the directions for use on the label.
[f]	Statement(s) must be included on the label written: <ul style="list-style-type: none"> (i) on a separate line or lines immediately below the cautionary statement “KEEP OUT OF REACH OF CHILDREN”; and (ii) in bold-face sanserif capital letters of uniform thickness; and (iii) in letters as least four tenths the height of the letters used for the signal heading; and (iv) with nothing else besides the statement written on the same line.
[g]	Statement(s), written in sanserif capital letters, must be included on the main label or as part of the directions for use.

6 Application

This instrument applies to a medicine that is a medicine in a prescribed class.

7 Medicines advisory statements

- (1) Subject to this section and section 8, the advisory statements mentioned in column 3 of the table in Schedule 1 to this instrument, are specified for the purposes of paragraph 3(5)(ca) of the Act in respect of a medicine in a prescribed class that contains the substance described in column 1 of the corresponding row and in the conditions set out in column 2.
- (2) In addition, the advisory statements mentioned in Schedule 1, where varied or, if more than one such statement applies, combined to form a simple sentence on the label of a medicine in a prescribed class in a manner that does not change the intent of the advisory statement, are specified for the purposes of paragraph 3(5)(ca) of the Act.

Note: Unless otherwise specified in column 2 of the table in Schedule 1, the requirements only apply if the substance is included in the medicine as an active ingredient.

8 Transitional arrangements

- (1) In this section:

former specification means the instrument specified in Schedule 2, as in force immediately before the commencement of this instrument.

transition period, for a medicine in a prescribed class, means the period beginning on the commencement of this instrument, and ending on 31 August 2020.

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- (2) Despite the repeal of the former specification in section 9 of this instrument, that specification continues to apply for the duration of the transition period in relation to the classes of medicines prescribed for the purposes of paragraph 3(5)(ca) of the Act, such that the advisory statements specified in the former specification may continue to be used on a label of a medicine, as an alternative to the advisory statements specified under section 7 of this instrument.

Note: During the transition period, the label of a medicine may contain the applicable advisory statements specified in Schedule 2 of the former specification instead of Schedule 1 to this instrument. However, once the transition period ceases, the label must contain the applicable advisory statements specified in Schedule 1.

9 Repeals

Each instrument that is specified in Schedule 2 to this instrument is repealed as set out in the applicable items in that Schedule.

Schedule 1—Required Advisory Statements for Medicine Labels No. 5

Note: See section 7.

Table: Required Advisory Statements for Medicine Labels No. 5

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Alclometasone	When included in Schedule 3 to the SUSMP	<ul style="list-style-type: none"> • CAUTION - Do not use for children under 2 years old unless a doctor has told you to. • Do not use in the eyes. • Do not use for acne. • Do not use under waterproof bandages unless a doctor has told you to. • Do not use for more than 7 days unless a doctor has told you to.
Alimemazine (trimeprazine) <i>Entry 1 of 2</i>	<p>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)</p> <p>when NOT separately specified in this table</p>	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Alimemazine (trimeprazine) <i>Entry 2 of 2</i>	<p>In oral medicines that are NOT indicated for cough cold or flu, 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)</p>	<ul style="list-style-type: none"> • 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.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Alpha hydroxy acids, including: <ul style="list-style-type: none"> citric acid and other fruit acids glycollic acid lactic acid 	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> 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.
Amethocaine (tetracaine) (Entry 1 of 2)	When included in Schedule 2 to the SUSMP and for dermal use	<ul style="list-style-type: none"> Do not apply to large areas of the body, except on the advice of a healthcare practitioner. If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Amethocaine (tetracaine) (Entry 2 of 2)	For the purpose of exclusion from the schedules to the SUSMP when in dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Ammonia and ammonium salts, including <ul style="list-style-type: none"> ammonium chloride ammonium bicarbonate ammonium carbonate (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> Do not give to children under 12 years of age. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ammonia and ammonium salts, including <ul style="list-style-type: none"> • ammonium chloride • ammonium bicarbonate • ammonium carbonate (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. • If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Anise oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> • in preparations containing more than 50 per cent of anise oil; and • packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
Antihistamines (Entry 1 of 5) including: <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Antihistamines <i>(Entry 2 of 5)</i> including: <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 <i>(Entry 3 of 5)</i> including: <ul style="list-style-type: none"> • Brompheniramine • Chlorphenamine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Pheniramine • Promethazine • Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> • which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6) 	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> – This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> – 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> – Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Antihistamines <i>(Entry 4 of 5)</i> including: <ul style="list-style-type: none"> • Brompheniramine • Chlorphenamine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Pheniramine • Promethazine • Triprolidine when NOT separately specified in this table	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • This medication may cause drowsiness. • Do not give to children under 'x' years of age. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> – Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Antihistamines <i>(Entry 5 of 5)</i> including: <ul style="list-style-type: none"> • Diphenhydramine • Doxylamine • Promethazine 	In oral medicines indicated for SHORT TERM USE IN INSOMNIA: <ul style="list-style-type: none"> • which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) <i>(Note: Antihistamine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Antihistamines (Entry 2 of 5)')</i>	<ul style="list-style-type: none"> • This product should be taken on medical or pharmacist advice. • Do not give to children under 'x' years of age. • <i>either (if the substance is in pregnancy category B or C):</i> <ul style="list-style-type: none"> - If pregnant or [likely/trying] to become pregnant, or if breastfeeding, consult a doctor or pharmacist before use. <i>or (if the substance is in pregnancy category A):</i> <ul style="list-style-type: none"> <i>either</i> <ul style="list-style-type: none"> - Not recommended for use by pregnant or breastfeeding women. <i>or</i> <ul style="list-style-type: none"> - If pregnant or 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.
Aspartame	When for oral ingestion and included in medicines as an active or excipient ingredient	<ul style="list-style-type: none"> • Phenylketonurics are warned that this product contains aspartame (phenylalanine).

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 1 of 3)	When NOT in combination with other therapeutically active substances (other than effervescent agents), or indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you are allergic to aspirin or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless a doctor has told you to, do not use in children under 12 years of age. • Unless a doctor has told you to, do not use in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever. • Unless advised by your doctor or pharmacist, do not use with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Unless a doctor has told you to, do not use for more than a few days at a time. • See a doctor before taking for thinning the blood or for your heart.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Aspirin (Entry 2 of 3)	When the preparation IS indicated for the prevention of cardiovascular disease or for the inhibition of platelet aggregation	<ul style="list-style-type: none"> • For use under medical supervision only. • Do not use if you have a stomach ulcer. • Do not use if you are allergic to aspirin or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless a doctor has told you to, do not use in children under 12 years of age. • Unless a doctor has told you to, do not use in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever. • Unless advised by your doctor or pharmacist, do not use with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • See a doctor before taking for thinning the blood or for your heart.
Aspirin (Entry 3 of 3)	When included in a schedule to the SUSMP and in combination with other therapeutically active substances (other than effervescent agents)	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you are allergic to aspirin or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless a doctor has told you to, do not use in children under 12 years of age. • Unless a doctor has told you to, do not use in children 12 to 16 years of age with or recovering from chicken pox, influenza or fever. • Unless advised by your doctor or pharmacist, do not use with other products containing aspirin or anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Unless a doctor has told you to, do not use for more than a few days at a time.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Atropa belladonna	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> • If the condition persists after two days of treatment, seek medical advice as soon as possible.
Atropine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> • If the condition persists after two days of treatment, seek medical advice as soon as possible.
<i>Azadirachta indica</i> (neem) (Entry 1 of 2)	For the purpose of exclusion from the schedules to the SUSMP when in preparations for dermal use and in a container fitted with a child resistant closure	<ul style="list-style-type: none"> • Not to be taken. • Keep out of reach of children. • Do not use if pregnant or likely to become pregnant.
<i>Azadirachta indica</i> including its extracts and derivatives (Entry 2 of 2)	When included in Schedule 6 to the SUSMP	<ul style="list-style-type: none"> • Do not use if pregnant or likely to become pregnant.
Azelastine	In preparations for topical ophthalmic or nasal administration	<ul style="list-style-type: none"> • If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.
Basil oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations or oils containing more than 5 per cent of methyl chavicol; and • packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Bay oil	<p>For the purpose of exclusion from the schedules to the SUSMP when</p> <ul style="list-style-type: none"> • in preparations containing more than 25 per cent of bay oil; and • packed in containers having: <ul style="list-style-type: none"> - a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or - a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN
Benzocaine (Entry 1 of 4)	In dermal preparations containing MORE than 2 per cent of total local anaesthetic substances	<ul style="list-style-type: none"> • Do not apply to large areas of the body, except on the advice of a healthcare practitioner. • If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Benzocaine (Entry 2 of 4)	In dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> • If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Benzocaine (Entry 3 of 4)	In lozenges	<ul style="list-style-type: none"> • Do not take hot food or drink if the mouth feels numb after taking this product as it may burn the mouth. • Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dentist.
Benzocaine (Entry 4 of 4)	In preparations for topical oral use EXCEPT lozenges	<ul style="list-style-type: none"> • Do not give to children under 2 years of age.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Benzoyl peroxide	In Schedule 2 to the SUSMP	<ul style="list-style-type: none"> • Keep from eyes, lips, mouth and sensitive areas of the neck. • If excessive swelling, irritation, redness or peeling occurs, discontinue use. • If these persist, consult a physician. • Avoid excessive exposure to sunlight and other sources of ultra violet light.
Benzydamine	In preparations for topical use or dermal use	<ul style="list-style-type: none"> • Do not use [this product/<i>insert name of product</i>] if you are allergic to benzydamine or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately.
Bergamot oil	For the purpose of exclusion from the schedules to the SUSMP; or when included in a schedule to the SUSMP	<ul style="list-style-type: none"> • Application to skin may increase sensitivity to sunlight.
Bromhexine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • Do not give to children under 12 years of age. • If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Bromhexine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. • <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. • If [coughing/symptoms] persist(s), consult your doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
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	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> • 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' years (where 'x' must not be less than 6)	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Brompheniramine (Entry 4 of 4)	<p>In oral preparations indicated for COUGH, COLD OR FLU:</p> <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • This medication may cause drowsiness. • Do not give to children under 'x' years of age. • and (if 'x' < 12) <ul style="list-style-type: none"> – Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Butoconazole	In preparations for vaginal use	<ul style="list-style-type: none"> • Do not use if you are pregnant. • See a doctor before use if you are diabetic. • Seek medical advice before first course of treatment. • See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days. • See a doctor if problem returns.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cajuput oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations or oils containing more than 25 per cent of cajuput oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
Camphor (Entry 1 of 3)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • included as a natural component in essential oils containing greater than 2.5 per cent of camphor but 10 per cent or less of camphor; and • packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN. • Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Camphor (Entry 2 of 3)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in essential oils when the camphor is present as a natural component of the oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN. • Do not apply to infants under 12 months of age except on the advice of a doctor or pharmacist.
Camphor (Entry 3 of 3)	<p>When:</p> <ul style="list-style-type: none"> • included in a schedule to the SUSMP, and • not in block, ball or pellet form, enclosed in a device which, in normal use, prevents removal or ingestion of its contents. 	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Can be fatal to children if sucked or swallowed. Avoid contact with eyes.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cassia oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Avoid contact with skin. • DO NOT SWALLOW. [g]
Cetirizine (Entry 1 of 2)	In preparations for oral use that are NOT specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. • If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.
Cetirizine (Entry 2 of 2)	In preparations for oral use specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> • This medication may cause drowsiness.
<i>Chelidonium majus</i>	When the preparation is for oral use.	<ul style="list-style-type: none"> • Warning: Greater Celandine may harm the liver in some people. • Use only under the supervision of a healthcare professional.
Chloramphenicol	In medicines for ophthalmic use	<ul style="list-style-type: none"> • Contact lens wearers should not use this product except on the advice of a doctor or optometrist. • If your eye infection does not improve within 48 hours, seek immediate medical advice. • Do not use in children under 2 years of age except on medical advice.
Chlorhexidine (Entry 1 of 2)	In topical products, including preparations for topical use on mucosal surfaces.	<ul style="list-style-type: none"> • Avoid contact with eyes. • If in eyes, rinse well with water. • WARNING – This product contains chlorhexidine. Severe allergic reactions can occur. Stop use if this occurs.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Chlorhexidine (Entry 2 of 2)	In topical products OTHER THAN preparations for topical use on mucosal surfaces.	<ul style="list-style-type: none"> • Avoid contact with eyes. • If in eyes, rinse well with water. • Mild irritation may occur; stop use if it becomes severe.
Chlorphenamine (previously Chlorpheniramine) (Entry 1 of 4)	<p>In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2)</p> <p>when NOT separately specified in this table</p>	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - 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)	<p>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)</p> <p>when NOT separately specified in this table</p>	<ul style="list-style-type: none"> • 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.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Chlorphenamine (Entry 3 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none">• which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> – This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> – 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> – 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: <ul style="list-style-type: none">• 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)	<ul style="list-style-type: none"> • This medication may cause drowsiness. • Do not give to children under 'x' years of age. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> – Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Choline salicylate	In preparations for topical oral use.	<ul style="list-style-type: none"> • Do not exceed the recommended dose. Excessive or prolonged use can be harmful.
Cimetidine	In Schedule 3 to the SUSMP	<ul style="list-style-type: none"> • Use only under medical supervision if you are taking other medicines. • CAUTION: This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks, consult a doctor.
Cinchocaine (Entry 1 of 2)	In preparations for rectal use only	<ul style="list-style-type: none"> • If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Cinchocaine (Entry 2 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> • Do not apply to large areas of the body, except on the advice of a healthcare practitioner • If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cineole	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations or oils containing more than 25 per cent of cineole (other than rosemary oil or camphor oil); and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
Cinnamon bark oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Avoid contact with skin • DO NOT SWALLOW. [g]

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Cinnamon leaf oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25 per cent of cinnamon leaf oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
<p>Citric acid and other fruit acids</p> <p><i>(See also Alpha hydroxy acids)</i></p>	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> • 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.
Clobetasone	In preparations for dermal use	<ul style="list-style-type: none"> • Do not use in the eyes. • Do not use for acne. • Do not use under waterproof bandages unless a doctor has told you to. • Do not use for more than 7 days unless a doctor has told you to. • CAUTION - Do not use for children under 12 years old unless a doctor has told you to.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Clotrimazole	In preparations for vaginal use	<ul style="list-style-type: none"> • Seek medical advice before first course of treatment. • See a doctor if you are pregnant or diabetic. • See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days. • See a doctor if problem returns.
Clove oil (Entry 1 of 2)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25 per cent of clove oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
Clove oil (Entry 2 of 2)	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Avoid contact with eyes. • DO NOT SWALLOW. [g]
Coal tar	In preparations for topical use	<ul style="list-style-type: none"> • Avoid contact with eyes. • If skin irritation occurs, discontinue use. • Do not use for prolonged periods except on the advice of a doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Codeine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> Do not give to children under 12 years of age.
Codeine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> Do not give to children under 'x' years of age. either (if 'x' is 11) <ul style="list-style-type: none"> Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
<i>Datura spp</i>	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> If the condition persists after two days of treatment, seek medical advice as soon as possible.
Desloratadine	In medicines for oral use	<ul style="list-style-type: none"> If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.
Dexchlorpheniramine (Entry 1 of 4)	<p>In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2)</p> <p>when NOT separately specified in this table</p>	<ul style="list-style-type: none"> either <ul style="list-style-type: none"> This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or <ul style="list-style-type: none"> 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) <ul style="list-style-type: none"> Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dexchlorpheniramine (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	<ul style="list-style-type: none"> 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.
Dexchlorpheniramine (Entry 3 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6) 	<ul style="list-style-type: none"> <i>either</i> <ul style="list-style-type: none"> This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. <i>or</i> <ul style="list-style-type: none"> 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. <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> This medication may cause drowsiness. Do not give to children under 'x' years of age. <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dextromethorphan (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> Do not give to children under 12 years of age. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Dextromethorphan (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> Do not give to children under 'x' years of age. either (if 'x' is 11) <ul style="list-style-type: none"> Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Dibromopropamide	In medicines for ophthalmic use	<ul style="list-style-type: none"> Contact lens wearers should not use this product except on the advice of a doctor or optometrist. If your eye infection does not improve within 48 hours, seek immediate medical advice.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diclofenac (Entry 1 of 3)	In preparations for oral use only in adults and children aged 12 years and over	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to diclofenac or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diclofenac (Entry 2 of 3)	In preparations that include indications for oral use in children under 12 years of age	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to diclofenac or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with other products containing diclofenac, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.
Diclofenac (Entry 4 of 4)	When the preparation is for dermal use	<ul style="list-style-type: none"> • Do not use [this product/<i>insert name of product</i>] if you are allergic to diclofenac or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor or pharmacist has told you to, do not use [this product/<i>insert name of product</i>] with other medicines that you are taking regularly.
Diethyltoluamide (DEET)	All, including where present as an excipient	<ul style="list-style-type: none"> • WARNING - May be dangerous, particularly to children, if you use large amounts on the skin, clothes or bedding or on large areas of the body, especially if you keep using it for a long time.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Dihydrocodeine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> Do not give to children under 12 years of age. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Dihydrocodeine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> Do not give to children under 'x' years of age. either (if 'x' is 11) <ul style="list-style-type: none"> Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Diphenhydramine (Entry 1 of 5)	<p>In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2)</p> <p>when NOT separately specified in this table</p>	<ul style="list-style-type: none"> either <ul style="list-style-type: none"> This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or <ul style="list-style-type: none"> 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) <ul style="list-style-type: none"> Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diphenhydramine (<i>Entry 2 of 5</i>)	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	<ul style="list-style-type: none"> 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 (<i>Entry 3 of 5</i>)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6) 	<ul style="list-style-type: none"> <i>either</i> <ul style="list-style-type: none"> This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. <i>or</i> <ul style="list-style-type: none"> 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. <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Diphenhydramine (<i>Entry 4 of 5</i>)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> This medication may cause drowsiness. Do not give to children under 'x' years of age. <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Diphenhydramine (<i>Entry 5 of 5</i>)	<p>In oral medicines indicated for SHORT TERM USE IN INSOMNIA:</p> <ul style="list-style-type: none"> • which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) <p>(<i>Note: Diphenhydramine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Diphenhydramine (Entry 2 of 5)'</i>)</p>	<ul style="list-style-type: none"> • This product should be taken on medical or pharmacist advice. • Do not give to children under 'x' years of age. • <i>either</i> <ul style="list-style-type: none"> – Not recommended for use by pregnant or breastfeeding women. • <i>or</i> <ul style="list-style-type: none"> – If pregnant or 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.
Diphenoxylate	In medicines for oral use	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> – This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> – 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 12 years of age. • If the condition persists after two days of treatment, seek medical advice as soon as possible. • Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
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	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - 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) when NOT separately specified in this table	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Doxylamine (Entry 4 of 5)	<p>In oral preparations indicated for COUGH, COLD OR FLU:</p> <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • This medication may cause drowsiness. • Do not give to children under 'x' years of age. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> – 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)	<p>In oral medicines indicated for SHORT TERM USE IN INSOMNIA:</p> <ul style="list-style-type: none"> • which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) <p><i>(Note: Doxylamine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Doxylamine (Entry 2 of 5)')</i></p>	<ul style="list-style-type: none"> • This product should be taken on medical or pharmacist advice. • Do not give to children under 'x' years of age. • <i>either</i> <ul style="list-style-type: none"> – Not recommended for use by pregnant or breastfeeding women. • <i>or</i> <ul style="list-style-type: none"> – If pregnant or 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.
Econazole	In preparations for vaginal use	<ul style="list-style-type: none"> • Seek medical advice before first course of treatment. • See a doctor if you are pregnant or diabetic. • See a doctor if no better after <i>[Insert number of days as per approved Product Information]</i> days. • See a doctor if problem returns.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Esomeprazole	In medicines for oral use	<ul style="list-style-type: none"> • CAUTION – This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.
Eucalyptus oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25 per cent of eucalyptus oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Eugenol (Entry 1 of 2)	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> • in preparations containing more than 25 per cent of eugenol; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
Eugenol (Entry 2 of 2)	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Avoid contact with eyes. • DO NOT SWALLOW. [g]

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Famciclovir	In medicines for oral use	<ul style="list-style-type: none"> • If you are taking other medicines regularly, consult your pharmacist or doctor before use. • If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine. • Do not take [this product/<i>insert name of product</i>] if you are allergic to famciclovir or penciclovir. • Do not take [this product/<i>insert name of product</i>] if you have problems with your immune system. • Do not take [this product/<i>insert name of product</i>] if you have kidney problems, unless advised by a doctor. • If you have high blood pressure, heart problems, liver problems, diabetes or other medical conditions, consult your pharmacist or doctor before use. • If you have symptoms and signs of an infection other than your cold sore, consult your pharmacist or doctor before use.
Famotidine	In medicines for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks, consult a doctor.
Fennel oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> • in preparations or oils containing more than 5 per cent of methyl chavicol; and • packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
Fexofenadine	In medicines for oral use	<ul style="list-style-type: none"> • If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Fluconazole	In oral medicines for treatment of vaginal candidiasis	<ul style="list-style-type: none"> • Seek medical advice before first course of treatment. • Do not use if pregnant or [trying/likely] to become pregnant. • See a doctor before use if you are diabetic. • Ask your doctor or pharmacist before use if you are taking warfarin. • See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days. • See a doctor if problem returns.
Fluorides (Entry 1 of 3)	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in dental hygiene products (other than pastes, powders or gels for the cleaning of teeth) containing 220 mg/kg or less of fluoride ion, in packs containing not more than 120 milligrams total fluoride fitted with a child-resistant closure 	<ul style="list-style-type: none"> • Do not swallow. • Do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.
Fluorides (Entry 2 of 3)	When included in a schedule to the SUSMP except oral fluoride supplements	<ul style="list-style-type: none"> • Do not swallow. • Do not use [this product/<i>insert name of product</i>] in children 6 years of age or less.
Fluorides (Entry 3 of 3)	In Schedule 2 to the SUSMP in oral preparations as fluoride supplements	<ul style="list-style-type: none"> • Do not use if pregnant • Use of this product is not necessary in areas supplied with fluoridated water • Do not use except on the advice of a dentist

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Flurbiprofen (Entry 1 of 2)	In oral preparations that do NOT include indications for use in children under 12 years of age	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to flurbiprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with other products containing flurbiprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Flurbiprofen (Entry 2 of 2)	In oral preparations that include indications for use in children under 12 years of age	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to flurbiprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with other products containing flurbiprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.
Folic acid	In preparations indicated for reducing the risk of having a child with spina bifida/neural tube defects	<ul style="list-style-type: none"> • Do not exceed the stated dose except on medical advice. • If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice.
Glycollic acid (See Alpha hydroxy acids)	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> • 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.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Guaifenesin (Guaiphenesin) (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> Do not give to children under 12 years of age. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Guaifenesin (Guaiphenesin) (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> Do not give to children under 'x' years of age. <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Hexachlorophane	In preparations for skin cleansing purposes containing 3 per cent or less of hexachlorophane.	<ul style="list-style-type: none"> For external washing only. Rinse skin thoroughly after use.
Hydrocortisone (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> CAUTION - do not use for children under 2 years old unless a doctor has told you to. Do not use in the eyes. Do not use for acne. Do not use under waterproof bandages unless a doctor has told you to. Do not use for more than 7 days unless a doctor has told you to.
Hydrocortisone (Entry 2 of 2)	In preparations for topical rectal use	<ul style="list-style-type: none"> CAUTION - do not use for children under 2 years old unless a doctor has told you to. Do not use for more than 7 days unless a doctor has told you to.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydrogen peroxide (Entry 1 of 3)	In concentrations of more than 3 per cent up to 10 per cent	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Irritant Avoid contact with eyes. • DO NOT SWALLOW. [g]
Hydrogen peroxide (Entry 2 of 3)	In concentrations of more than 10 per cent up to 20 per cent	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Irritant Attacks eyes - protect eyes when using.
Hydrogen peroxide (Entry 3 of 3)	In concentrations of more than 20 per cent.	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Corrosive Attacks eyes - protect eyes when using Avoid contact with skin.
Hydroquinone	In Schedule 2 to the SUSMP	<ul style="list-style-type: none"> • WARNING - If a pigmented spot or mole has recently become darker, changed colour, become enlarged or itchy, or bleeds, do not use this product, see your doctor immediately. • Do not use on children. • Do not use near the eyes. • Mild irritation may occur; stop use if it becomes severe. • If fading is not evident in three months, seek doctor's advice. • Do not exceed recommended dose. Excessive or prolonged use should be avoided because darkening of the skin can occur.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna <i>(Entry 1 of 3)</i>	Where the MRDD contains MORE than 10 milligrams and the product IS promoted or marketed as a laxative	<ul style="list-style-type: none"> • Not recommended for use by children under 12 years of age. • If symptoms persist, seek advice from a health care practitioner. • Drink plenty of water. • Prolonged use may cause serious bowel problems. • Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product.
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna <i>(Entry 2 of 3)</i>	Where the MRDD contains MORE than 10 milligrams and the product IS NOT promoted or marketed as a laxative	<ul style="list-style-type: none"> • Not recommended for use by children under 12 years of age. • If symptoms persist, seek advice from a health care practitioner. • This product may have a laxative effect. • Prolonged use may cause serious bowel problems. • Do not use when abdominal pain, nausea or vomiting are present, or if you develop diarrhoea. If you are pregnant or breast feeding, seek the advice of a healthcare professional before taking this product. • This product contains <i>[insert name of the herb(s) or the chemical component(s)]</i>.
Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna <i>(Entry 3 of 3)</i>	Where the MRDD contains 10 milligrams OR LESS and the product IS promoted or marketed as laxative	<ul style="list-style-type: none"> • Not recommended for use by children under 12 years of age. • If symptoms persist, seek advice from a health care practitioner. • Drink plenty of water. • Prolonged use may cause serious bowel problems.
8-Hydroxyquinoline (including salts and derivatives)	In preparations for internal use	<ul style="list-style-type: none"> • Do not take for periods longer than four weeks except on medical advice.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Hyoscine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> • If the condition persists after two days of treatment, seek medical advice as soon as possible.
Hyoscyamine	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> • If the condition persists after two days of treatment, seek medical advice as soon as possible. • Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist
<i>Hyoscyamus niger</i>	In preparations for oral use, EXCEPT where indicated exclusively for the treatment of motion/travel sickness	<ul style="list-style-type: none"> • If the condition persists after two days of treatment, seek medical advice as soon as possible.
Ibuprofen (Entry 1 of 6)	For the purpose of exclusion from the schedules to the SUSMP, when the preparation is for oral use in adults and children aged 12 years and over.	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Unless a doctor has told you to, do not use if you are aged 65 years or over.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 2 of 6)	When included in a schedule to the SUSMP for oral use in adults and children aged 12 years and over	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 3 of 6)	For the purpose of exclusion from the schedules to the SUSMP, for oral use in children under 12 years of age	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting. • Unless a doctor has told you to, do not use if you are aged 65 years or over. • Unless a doctor has told you to, do not use in children 6 years of age or less.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 4 of 6)	When included in a schedule to the SUSMP for oral use in children under 12 years of age	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ibuprofen (Entry 5 of 6)	In combination with paracetamol, in medicines for oral use	<ul style="list-style-type: none"> • Do not give to children under 12 years of age. • Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. • Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if pregnant or trying to become pregnant. • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless a doctor has told you to, do not use if you are aged 65 years or over. • Do not take with other products containing paracetamol, ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly, unless advised to do so by a doctor or pharmacist. • If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.
Ibuprofen (Entry 6 of 6)	In preparations for dermal use	<ul style="list-style-type: none"> • Do not use [this product/<i>insert name of product</i>] if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor or pharmacist has told you to, do not use [this product/<i>insert name of product</i>] with other medicines that you are taking regularly.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Indomethacin	In preparations for external use	<ul style="list-style-type: none"> Do not use [this product/<i>insert name of product</i>] if you are allergic to indomethacin or other anti-inflammatory medicines. If you get an allergic reaction, stop taking and see your doctor immediately. Unless a doctor or pharmacist has told you to, do not use this product with other medicines that you are taking regularly.
Iodine (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> If skin irritation or rash occurs, discontinue use immediately.
Iodine (Entry 2 of 2)	In preparations for internal use containing 300 micrograms or more of iodine per recommended daily dose	<ul style="list-style-type: none"> CAUTION - Total iodine intake may exceed recommended level when taking this preparation. WARNING - Contains iodine - do not take when pregnant except on physician's advice.
Ipecacuanha (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> Do not give to children under 12 years of age. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Ipecacuanha (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> Do not give to children under 'x' years of age. either (if 'x' is 11) <ul style="list-style-type: none"> Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Ipratropium bromide	In metered aerosols	<ul style="list-style-type: none"> This preparation should be part of an overall treatment plan regularly assessed with your doctor.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ketoprofen (Entry 1 of 3)	In preparations for oral use in adults and children aged 12 years and over	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ketoprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Ketoprofen (Entry 2 of 3)	In preparations for oral use in children under 12 years of age	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ketoprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with products containing ketoprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.
Ketoprofen (Entry 3 of 3)	In preparations for dermal use	<ul style="list-style-type: none"> • Do not use [this product/<i>insert name of product</i>] if you are allergic to ketoprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor or pharmacist has told you to, do not use this product with other medicines that you are taking regularly.
Lactic acid (See Alpha hydroxy acids)	When used as active ingredients in preparations for topical use	<ul style="list-style-type: none"> • 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

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Lansoprazole	In medicines for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.
Lemon oil	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> • Application to skin may increase sensitivity to sunlight.
<i>Leptospermum scoparium</i> oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25 per cent of <i>Leptospermum scoparium</i> oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
Levocabastine (Entry 1 of 2)	In eye or nasal preparations containing 0.5 milligrams/millilitre or less of levocabastine	<ul style="list-style-type: none"> • Do not use if pregnant.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Levocabastine (Entry 2 of 2)	In eye or nasal preparations containing MORE THAN 0.5 milligrams per millilitre of levocabastine.	<ul style="list-style-type: none"> Do not use if pregnant. either <ul style="list-style-type: none"> This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or <ul style="list-style-type: none"> This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery.
Levocetirizine (Entry 1 of 2)	In preparations for oral use labelled for use in adults	<ul style="list-style-type: none"> either <ul style="list-style-type: none"> This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. or <ul style="list-style-type: none"> This medication may cause drowsiness and may increase the effects of alcohol. If affected do not drive a motor vehicle or operate machinery. If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.
Levocetirizine (Entry 2 of 2)	In preparations for oral use specifically labelled for use only in children (between 1 year and 12 years of age)	<ul style="list-style-type: none"> This medication may cause drowsiness.
Lidocaine (Lignocaine) (Entry 1 of 3)	In dermal preparations containing MORE THAN 2 per cent of total local anaesthetic substances	<ul style="list-style-type: none"> Do not apply to large areas of the body, except on the advice of a healthcare practitioner. If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Lidocaine (Lignocaine) (Entry 2 of 3)	In dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Lidocaine (Lignocaine) (Entry 3 of 3)	In lozenges	<ul style="list-style-type: none"> Do not take hot food or drink if the mouth feels numb after taking this product as it may burn the mouth. Do not give to children under 6 years of age, unless recommended by a doctor, pharmacist or dentist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Lime oil	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> • Application to skin may increase sensitivity to sunlight.
Lindane	In preparations for external use	<ul style="list-style-type: none"> • Do not use on broken skin. • Ask your doctor or pharmacist before use. • This preparation should be used with caution on infants, small children and pregnant or breastfeeding women.
Loperamide hydrochloride	In medicines for oral use	<ul style="list-style-type: none"> • If the condition persists after two days of treatment, seek medical advice as soon as possible. • If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine. • Do not give to children under 12 years of age. • Drink plenty of fluids as fluid and electrolyte depletion may occur with diarrhoea. If dehydration is suspected seek medical attention. • Do not take if you have a medical condition where constipation should be avoided. • See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have a fever, severe stomach pain, bloody diarrhoea or ongoing condition affecting the bowel.
Loratadine	In medicines for oral use	<ul style="list-style-type: none"> • If you are pregnant or breastfeeding, check with your doctor or pharmacist before using this medicine.
Marjoram oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations containing more than 50 per cent of marjoram oil; and • packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Mefenamic acid	When indicated exclusively for the treatment of dysmenorrhoea	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to mefenamic acid or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with other products containing mefenamic acid, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.
Melaleuca oil	<p>For the purpose of exclusion from the schedules to the SUSMP when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25 per cent of melaleuca oil; and • when packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert; or – a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Metoclopramide	In medicines for oral use	<ul style="list-style-type: none"> Do not use in children and adolescents aged under 18 years. Tell your doctor or pharmacist before use if you are taking other medicines. Do not use if you have epilepsy [(seizures)/(fits)].
Methoxamine	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> If congestion persists consult your doctor or pharmacist. Do not use for more than three days at a time unless advised by a doctor or pharmacist. Frequent or prolonged use may cause nasal congestion to recur or worsen.
Miconazole (Entry 1 of 2)	In preparations for vaginal use	<ul style="list-style-type: none"> Seek medical advice before first course of treatment. See a doctor before use if you are pregnant or diabetic. Ask your doctor or pharmacist before use if you are taking warfarin. See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days. See a doctor if problem returns.
Miconazole (Entry 2 of 2)	In preparations for topical oral use	<ul style="list-style-type: none"> Ask your doctor or pharmacist before use if you are taking warfarin.
Naphazoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> If congestion persists consult your doctor or pharmacist. Do not use for more than three days at a time unless advised by a doctor or pharmacist. Frequent or prolonged use may cause nasal congestion to recur or worsen.
Naphazoline (Entry 2 of 2)	In topical eye preparations	<ul style="list-style-type: none"> Prolonged use may be harmful. Consult a doctor or pharmacist if using other eye products. Do not use if you have glaucoma or other serious eye conditions. If symptoms persist, consult a doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Naproxen (Entry 1 of 2)	In preparations for oral use in adults and children aged 12 years and over	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to naproxen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Naproxen (Entry 2 of 2)	When the preparation includes indications for oral use in children under 12 years of age	<ul style="list-style-type: none"> • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to naproxen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless advised by your doctor or pharmacist, do not use with other products containing naproxen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly. • Do not use for more than a few days at a time unless a doctor has told you to. Do not exceed the recommended dose. Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if trying to become pregnant, or during the first 6 months of pregnancy, except on doctor's advice. Do not use at all during the last 3 months of pregnancy. • Ask your doctor or pharmacist before use of the medicine in children suffering from dehydration through diarrhoea and/or vomiting.
Nasal decongestant preparations, including: <ul style="list-style-type: none"> • Methoxamine • Naphazoline • Oxymetazoline • Phenylephrine • Tetrahydrozoline • Tramazoline • Tymazoline • Xylometazoline 	When in nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
Nizatidine	In medicines for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks, consult a doctor.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Nutmeg oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> • in preparations containing more than 50 per cent of nutmeg oil; and • packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
Nystatin	In preparations for vaginal use	<ul style="list-style-type: none"> • See a doctor if you are pregnant or diabetic. • Seek medical advice before first course of treatment. • If getting better, keep using for [<i>insert number of days as per approved Product Information</i>] days. • See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days. • See a doctor if problem returns.
Omeprazole	In preparations for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.
Orange oil (bitter)	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> • Application to skin may increase sensitivity to sunlight.
Oxymetazoline (Entry 1 of 4)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Oxymetazoline (Entry 2 of 4) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.
Oxymetazoline (Entry 3 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen. • Do not give to children under 12 years of age.
Oxymetazoline (Entry 4 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen. • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. • <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Pantoprazole	In medicines for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Paracetamol (Entry 1 of 3)	For the purpose of exclusion from the schedules to the SUSMP	<ul style="list-style-type: none"> • Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. • Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage. • Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.
Paracetamol (Entry 2 of 3)	In Schedule 2 or 3 to the SUSMP	<ul style="list-style-type: none"> • <ul style="list-style-type: none"> - Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. <i>and / or</i> - Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage. • Do not take with other products containing paracetamol, unless advised to do so by a doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Paracetamol (Entry 3 of 3)	In combination with ibuprofen, in medicines for oral use	<ul style="list-style-type: none"> • Do not give to children under 12 years of age. • Adults: Keep to the recommended dose. Do not take this medicine for longer than a few days at a time unless advised to by a doctor. • Children and adolescents: Keep to the recommended dose. Do not give this medicine for longer than 48 hours at a time unless advised to by a doctor. • Excessive use can be harmful and increase the risk of heart attack, stroke or liver damage. • Do not use if pregnant or trying to become pregnant. • Do not use if you have a stomach ulcer. • Do not use if you have impaired kidney function. • Do not use if you have heart failure. • Do not use if you are allergic to ibuprofen or other anti-inflammatory medicines. • If you get an allergic reaction, stop taking and see your doctor immediately. • Unless a doctor has told you to, do not use if you have asthma. • Unless a doctor has told you to, do not use if you are aged 65 years or over. • Do not take with other products containing paracetamol, ibuprofen, aspirin or other anti-inflammatory medicines or with medicines that you are taking regularly, unless advised to do so by a doctor or pharmacist. • If an overdose is taken or suspected, ring the Poisons Information Centre (Australia 13 11 26, New Zealand 0800 764 766) or go to hospital straight away even if you feel well because of the risk of delayed, serious liver damage.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pennyroyal oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> • in preparations containing more than 4 per cent of d-pulegone; and • when packed in containers having a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
Pentoxyverine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • Do not give to children under 12 years of age. • If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Pentoxyverine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. • <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. • If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Permanganates (see also Potassium permanganate)	When included in Schedule 6 to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Corrosive Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
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	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pheniramine (Entry 4 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • This medication may cause drowsiness. • Do not give to children under 'x' years of age. • and (if 'x' < 12) <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Phenol and any other homologue of phenol	When included in Schedule 2 to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Avoid contact with eyes Avoid contact with skin. • DO NOT SWALLOW. [g]
Phenylephrine (Entry 1 of 7)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
Phenylephrine (Entry 2 of 7) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.
Phenylephrine (Entry 3 of 7)	In oral preparations that are NOT indicated for cough, cold or flu	<ul style="list-style-type: none"> • See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication. • This product may cause sleeplessness.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Phenylephrine (Entry 4 of 7)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication. • This product may cause sleeplessness. • Do not give to children under 12 years of age.
Phenylephrine (Entry 5 of 7)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication. • This product may cause sleeplessness. • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Phenylephrine Entry 6 of 7)	In nasal decongestant preparations for topical use indicated for cough, cold or flu, which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen. • Do not give to children under 12 years of age.
Phenylephrine (Entry 7 of 7)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children under 'x' years of age, except on the advice of a doctor, pharmacist or nurse practitioner. <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pholcodine (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu, and the preparation does not include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> Do not give to children under 12 years of age. If [coughing/symptoms] persist(s) consult your doctor or pharmacist.
Pholcodine (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> Do not give to children under 'x' years of age. either (if 'x' is 11) <ul style="list-style-type: none"> Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If [coughing/symptoms] persist(s) consult your doctor or pharmacist.
<i>Piper methysticum</i>	For the purpose of exclusion from the schedules to the SUSMP in medicines for oral use	<ul style="list-style-type: none"> Not recommended for use by pregnant or lactating women WARNING: Not for prolonged use If symptoms persist, seek advice from a health care practitioner. May harm the liver.
Podophyllin (Entry 1 of 2)	In liquid preparations OTHER THAN preparations specifically for use on the anal or genital areas	<ul style="list-style-type: none"> WARNING - Do not use on face or on anal or genital areas except on doctor's advice.
Podophyllin (Entry 1 of 2)	In solid or semi-solid preparations OTHER THAN preparations specifically for use on the anal or genital areas	<ul style="list-style-type: none"> WARNING - Do not use on face or on anal or genital areas.
Podophyllotoxin (Entry 1 of 2)	In liquid preparations OTHER THAN preparations specifically for use on the anal or genital areas.	<ul style="list-style-type: none"> WARNING - Do not use on face or on anal or genital areas except on doctor's advice.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Podophyllotoxin (Entry 2 of 2)	In solid or semi-solid preparations OTHER THAN preparations specifically for use on the anal or genital areas.	<ul style="list-style-type: none"> • WARNING - Do not use on face or on anal or genital areas.
Potassium permanganate	In Schedule 6 to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] or - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Corrosive Avoid contact of the crystals or strong solutions with the eyes, mouth, nose and other mucous membranes.
Povidone-iodine	In preparations for dermal use	<ul style="list-style-type: none"> • If skin irritation or rash occurs, discontinue use immediately.
Promethazine (Entry 1 of 5)	<p>In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2)</p> <p>when NOT separately specified in this table</p>	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
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	<ul style="list-style-type: none"> 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.
Promethazine (Entry 3 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6) 	<ul style="list-style-type: none"> <i>either</i> <ul style="list-style-type: none"> This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. <i>or</i> <ul style="list-style-type: none"> 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. <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Promethazine (Entry 4 of 5)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> 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) 	<ul style="list-style-type: none"> This medication may cause drowsiness. Do not give to children under 'x' years of age. <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Promethazine (Entry 5 of 5)	<p>In oral medicines indicated for SHORT TERM USE IN INSOMNIA:</p> <ul style="list-style-type: none"> • which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) <p><i>(Note: Promethazine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Promethazine (Entry 2 of 5))'</i></p>	<ul style="list-style-type: none"> • This product should be taken on medical or pharmacist advice. • Do not give to children under 'x' years of age. • If pregnant or [likely/trying] to become pregnant, or 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.
Propamidine	In medicines for ophthalmic use	<ul style="list-style-type: none"> • Contact lens wearers should not use this product except on the advice of a doctor or optometrist. • If your eye infection does not improve within 48 hours, seek immediate medical advice.
Proton pump inhibitors including: <ul style="list-style-type: none"> • Esomeprazole • Lansoprazole • Omeprazole • Pantoprazole • Rabeprazole 	In medicines for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.
Pseudoephedrine (Entry 1 of 3)	When the preparation is NOT indicated for use for cough, cold or flu	<ul style="list-style-type: none"> • See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication. • [This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pseudoephedrine (<i>Entry 2 of 3</i>)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication. • [This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed. • Do not give to children under 12 years of age.
Pseudoephedrine (<i>Entry 3 of 3</i>)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • See your doctor or pharmacist before taking [this product/<i>insert name of product</i>] if you have high blood pressure or heart problems or are taking antidepressant medication. • [This product/<i>insert name of product</i>] may cause sleeplessness if it is taken up to several hours before going to bed. • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Psyllium	In medicines for oral ingestion which include dosage instructions for children	<ul style="list-style-type: none"> • Should only be used for children on medical advice.
Pyridoxal (<i>see also Vitamin B6, Vitamins</i>) (<i>Entry 1 of 2</i>)	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> • WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Pyridoxal (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI- INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> • WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B6.
Pyridoxine (see also Vitamin B6, Vitamins) (Entry 1 of 2)	In SINGLE- INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> • WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
Pyridoxine (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI- INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams per recommended daily dose	<ul style="list-style-type: none"> • WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B.
Pyrithione zinc	In preparations for external use for treatment of the scalp	<i>either</i> <ul style="list-style-type: none"> • Keep out of eyes. <i>or</i> <ul style="list-style-type: none"> • If in eyes, rinse well with water.
Rabeprazole	In medicines for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.
Ranitidine	Medicines for oral use	<ul style="list-style-type: none"> • CAUTION - This preparation is for the relief of minor and temporary ailments and should be used strictly as directed. • If symptoms persist or recur within two weeks, consult a doctor.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Safrole	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Avoid contact with eyes.
Sage oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> • in preparations containing more than 4 per cent of thujone; and • packed in containers having a nominal capacity of 15 millilitres or less, fitted with a restricted flow insert and child-resistant closure 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN. • NOT TO BE TAKEN.
Salbutamol	In metered aerosols or in dry powder formulations	<ul style="list-style-type: none"> • This preparation should be part of an overall treatment plan regularly assessed with your doctor.
Sassafras oil	When included in a schedule to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Avoid contact with eyes.
Senega (Entry 1 of 2)	In oral preparations indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • Do not give to children under 12 years of age. • If [coughing/symptoms] persist(s), consult your doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Senega (Entry 2 of 2)	In oral preparations indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> Do not give to children under 'x' years of age. either (if 'x' is 11) <ul style="list-style-type: none"> Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. or (if 'x' is 6, 7, 8, 9 or 10) <ul style="list-style-type: none"> Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner. If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
Silver (see also Silver salts)	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> in chewing gum containing 5 milligrams or less of silver per dosage unit; or in solutions for oral use containing 0.3 per cent or less of silver 	<ul style="list-style-type: none"> Overuse may stain skin or mouth.
Silver salts (see also Silver)	In smoking deterrents.	<ul style="list-style-type: none"> WARNING - Overuse may stain the skin or mouth.
Sodium fluoride (see also Fluorides)	In preparations for ingestion when in Schedule 2 to the SUSMP	<ul style="list-style-type: none"> Use of this product is not necessary in areas supplied with fluoridated water.
Star anise oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> in preparations containing more than 50 per cent of star anise oil; and packed in containers having a nominal capacity of 50 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> KEEP OUT OF REACH OF CHILDREN.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Sulfacetamide	In medicines for ophthalmic use	<ul style="list-style-type: none"> • Contact lens wearers should not use this product except on the advice of a doctor or optometrist. • If your eye infection does not improve within 48 hours, seek immediate medical advice.
<i>Symphytum</i> spp	In Schedule 5 to the SUSMP	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS [f] • <i>or</i> <ul style="list-style-type: none"> - READ SAFETY DIRECTIONS BEFORE OPENING AND USING. [f] • SAFETY DIRECTIONS Do not use on broken skin Do not use under occlusive dressing. • DO NOT SWALLOW. [g]
Terbutaline	In metered aerosols	<ul style="list-style-type: none"> • This preparation should be part of an overall treatment plan regularly assessed with your doctor.
Tetracaine (amethocaine) (Entry 1 of 2)	When included in Schedule 2 to the SUSMP and for dermal use	<ul style="list-style-type: none"> • Do not apply to large areas of the body, except on the advice of a healthcare practitioner. • If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Tetracaine (amethocaine) (Entry 2 of 2)	For the purpose of exclusion from the schedules to the SUSMP when in dermal preparations containing 2 per cent OR LESS of total local anaesthetic substances	<ul style="list-style-type: none"> • If skin irritation occurs, discontinue use and seek advice from your doctor or pharmacist.
Tetrahydrozoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
Tetrahydrozoline (Entry 2 of 2) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Thyme oil	For the purpose of exclusion from the schedules to the SUSMP when: <ul style="list-style-type: none"> • in preparations containing more than 50 per cent of thyme oil; and • packed in containers having a nominal capacity of 25 millilitres or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
Tioconazole	In preparations for vaginal use	<ul style="list-style-type: none"> • Do not use if you are pregnant. • See a doctor before use if you are diabetic. • Seek medical advice before first course of treatment. • See a doctor if no better after [<i>Insert number of days as per approved Product Information</i>] days. • See a doctor if problem returns.
Tramazoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
Tramazoline (Entry 2 of 2) (See also vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.
Triamcinolone	In topical preparations for the treatment of mouth ulcers	<i>either</i> <ul style="list-style-type: none"> • See a [doctor / doctor or dentist] if no better after [<i>Insert number of days as per approved Product Information</i>] days. <i>or</i> <ul style="list-style-type: none"> • If symptoms persist beyond 5 days consult a [doctor / doctor or dentist].

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
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	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> • 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: • which include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 6)	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - This medication may cause drowsiness. If affected do not drive a vehicle or operate machinery. Avoid alcohol. • <i>or</i> <ul style="list-style-type: none"> - 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. • <i>and (if 'x' < 12)</i> <ul style="list-style-type: none"> - Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Tripolidine (Entry 4 of 4)	In oral preparations indicated for COUGH, COLD OR FLU: <ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • This medication may cause drowsiness. • Do not give to children under 'x' years of age. • and (if 'x' < 12) <ul style="list-style-type: none"> – Do not give to children between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Tymazoline (Entry 1 of 2)	In nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
Tymazoline (Entry 2 of 2) (See also Vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.
Vasoconstrictor eye drops including: <ul style="list-style-type: none"> • Naphazoline • Oxymetazoline • Phenylephrine • Tetrahydrozoline • Tramazoline • Tymazoline • Xylometazoline 	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.
Vegetable oil phytosterol esters	In preparations for oral ingestion	<ul style="list-style-type: none"> • Not suitable for use by pregnant or lactating women. • There is no benefit from taking more than 3 g/day of phytosterols from all sources.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Vitamin A (See also Vitamins)	In medicines for oral use that are labelled to be used by females of childbearing age containing MORE THAN: <ul style="list-style-type: none"> • 33 micrograms retinol equivalents of vitamin A per dosage unit of a divided preparation; or • 33 micrograms retinol equivalents of vitamin A per gram of an undivided preparation 	<ul style="list-style-type: none"> • The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men. • WARNING – When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects. [c] • If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist. [c]
Vitamin B6 • pyridoxal • pyridoxine (Entry 1 of 2) (See also Vitamins)	In SINGLE-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams of [pyridoxine / pyridoxal] per recommended daily dose	<ul style="list-style-type: none"> • WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
Vitamin B6 • pyridoxal • pyridoxine (Entry 2 of 2) (See also Vitamins)	In MULTI-INGREDIENT preparations containing 200 milligrams or less but more than 50 milligrams of [pyridoxine / pyridoxal] per recommended daily dose	<ul style="list-style-type: none"> • WARNING – Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. Contains vitamin B6.
Xylometazoline (Entry 1 of 4)	When in nasal decongestant preparations for topical use	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.

Column 1 Substance(s)	Column 2 Conditions	Column 3 Required statement(s)
Xylometazoline (Entry 2 of 4) (See also Vasoconstrictor eye drops)	In topical eye preparations	<ul style="list-style-type: none"> • Prolonged use may be harmful. • Consult a doctor or pharmacist if using other eye products. • Do not use if you have glaucoma or other serious eye conditions. • If symptoms persist, consult a doctor or pharmacist.
Xylometazoline (Entry 3 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which DO NOT include dosage instructions for children aged under 12 years	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen. • Do not give to children under 12 years of age.
Xylometazoline (Entry 4 of 4)	In nasal decongestant preparations for topical use indicated for cough, cold or flu which include dosage instructions for children aged from 'x' to 11 years (where 'x' is 6, 7, 8, 9, 10 or 11)	<ul style="list-style-type: none"> • If congestion persists, consult your doctor or pharmacist. • Do not use for more than three days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen. • Do not give to children under 'x' years of age. • <i>either (if 'x' is 11)</i> <ul style="list-style-type: none"> - Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner. • <i>or (if 'x' is 6, 7, 8, 9 or 10)</i> <ul style="list-style-type: none"> - Do not give to children aged between 'x' and 11 years of age, except on the advice of a doctor, pharmacist or nurse practitioner.
Zinc compounds	In preparations for internal use with a recommended daily dose of more than 25 milligrams of zinc	<p><i>either</i></p> <ul style="list-style-type: none"> • WARNING - This medication may be dangerous when used in large amounts or for a long period. <p><i>or</i></p> <ul style="list-style-type: none"> • WARNING – Contains zinc, which may be dangerous when used in large amounts or for a long period.

Schedule 2—Repeals

Medicines Advisory Statements Specification 2017

1 The whole of the instrument

Repeal the instrument.