



Therapeutic Goods (Medicines Advisory Statements) Specification 2021

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

Dated 22 December 2021

Dr Jane Cook
First Assistant Secretary
Medicines Regulation Division
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1 Name

This instrument is the *Therapeutic Goods (Medicines Advisory Statements) Specification 2021*.

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 January 2022.	1 January 2022

Note: This table relates only to the provisions of this instrument as originally made.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;
- (d) supply;
- (e) 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 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:

- (a) products obtained from natural raw materials by distillation with water or steam or from the epicarp of citrus fruits by a mechanical process, or by dry distillation; or
- (b) oils of equivalent composition to products mentioned in paragraph (a) that are derived through synthetic means; or
- (c) prepared mixtures of oils of equivalent composition to products mentioned in paragraph (a) that comprise 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.

Regulations means the *Therapeutic Goods Regulations 1990*.

signal words, in relation to a substance included in a schedule to the current Poisons Standard, means the signal word or words as specified in subsection 5(4).

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

References to substances

- (1) In this instrument, unless the contrary intention appears, a reference to a substance includes the following:
 - (a) that substance prepared from natural sources or artificially;

- (b) if the substance is a plant (other than a plant included in Schedule 8 or 9 to the current Poisons Standard)—that plant or any part of that plant when packed or prepared for therapeutic use;
- (c) every salt, active principle or derivative of the substance, including esters and ethers, and every salt of such an active principle or derivative;
- (d) every alkaloid of the substance and every salt of such an alkaloid;
- (e) every stereoisomer of the substance and every salt of such a stereoisomer, other than where the stereoisomer is defined in the substance name (for example, dextromethorphan);
- (f) a preparation or admixture containing any proportion of the substance;

but does not include:

- (g) a preparation or product included in Appendix A of the current Poisons Standard; or
- (h) a substance included in Appendix G of the current Poisons Standard at a concentration not exceeding the concentration specified in that Appendix in relation to the substance; or
- (i) any other substance included in Schedules 1 to 6 to the current Poisons Standard, 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 current Poisons Standard.

References to concentration, strength or quantity of substances

- (2) In this instrument, unless the contrary intention appears, for a reference to a concentration, strength or quantity 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; and
 - (b) the expression “1%” 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.

References to symbols

- (3) A reference in column 4 of the table in Schedule 1, to a symbol in column 2 of an item in the following table, has the meaning set out in column 3 of that item.

Meaning of symbols		
Column 1	Column 2	Column 3
Item	Symbol	Meaning
1	[c]	Statements must be included at the beginning of the directions for use on the label
2	[f]	Statements must be included on the label written: <ul style="list-style-type: none"> (a) on a separate line or lines immediately below the

Meaning of symbols		
Column 1	Column 2	Column 3
Item	Symbol	Meaning
		cautionary statement “KEEP OUT OF REACH OF CHILDREN”; and
		(b) in bold-face sanserif capital letters of uniform thickness; and
		(c) in letters at least four tenths the height of the letters used for the signal words; and
		(d) with no other statement written on the same line
3	[g]	Statements, written in sanserif capital letters, must be included on the main label or as part of the directions for use

Signal words

- (4) The signal word or words for a substance included in a schedule to the current Poisons Standard mentioned in column 2 of an item in the following table, that is to be used for the purpose in column 3 of that item, are specified in column 4 of that item.

Signal word or words for substances			
Column 1	Column 2	Column 3	Column 4
Item	Schedule to the current Poisons Standard	Purpose	Signal word or words
1	Schedule 2	for any purpose	PHARMACY MEDICINE
2	Schedule 3	for any purpose	PHARMACIST ONLY MEDICINE
3	Schedule 4	for human use	PRESCRIPTION ONLY MEDICINE
4	Schedule 5	for any purpose	CAUTION
5	Schedule 6	for any purpose	POISON
6	Schedule 7	for any purpose	DANGEROUS POISON
7	Schedule 8	for any purpose	CONTROLLED DRUG

6 Application

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

7 Medicines advisory statements

- (1) Subject to subsection (2), the advisory statements mentioned in column 4 of an item in the table in Schedule 1, are specified in relation to a medicine in a prescribed class that contains the substance described in column 2 of that item, in the circumstances set out in column 3 of that item, for the purposes of paragraph 3(5)(ca) of the Act.

Alternative statements

- (2) The following advisory statements are specified in relation to a medicine in a prescribed class for the purposes of paragraph 3(5)(ca) of the Act, as an alternative to the advisory statements specified in relation to the medicine by subsection (1):
- (a) the advisory statements specified by subsection (1) in relation to the medicine, as varied in a manner that does not change the intent of the advisory statements;
 - (b) if more than one advisory statement is specified by subsection (1) in relation to the medicine—the advisory statements combined to form a simple sentence in a manner that does not change the intent of each advisory statement.

Note: Unless otherwise specified in column 3 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 *Therapeutic Goods (Medicines Advisory Statements) Specification 2019*, as in force immediately before the commencement of this instrument.

transition period means the period beginning on the commencement of this instrument and ending on 30 June 2023.

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

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

9 Repeals

The *Therapeutic Goods (Medicines Advisory Statements) Specification 2019* is repealed.

Schedule 1—Required Advisory Statements for Medicine Labels No. 6

Note: See section 7.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
1	Alclometasone	When included in 3 to the current Poisons Standard	<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 Schedule told you to. • Do not use for more than 7 days unless a doctor has told you to.
2	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. • If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
3	Alimemazine (trimeprazine) <i>Entry 2 of 2</i>	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)	<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. • If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
4	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.
5	Amethocaine (tetracaine) <i>(Entry 1 of 2)</i>	When included in Schedule 2 to the current Poisons Standard 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.
6	Amethocaine (tetracaine) <i>(Entry 2 of 2)</i>	For the purpose of exclusion from the schedules to the current Poisons Standard when in dermal preparations containing 2% 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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
7	Ammonia and ammonium salts, including <ul style="list-style-type: none"> • ammonium chloride • ammonium bicarbonate • ammonium carbonate <i>(Entry 1 of 2)</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"> • Do not give to children under 12 years of age. • If [coughing/symptoms] persist(s), consult your doctor or pharmacist.
8	Ammonia and ammonium salts, including <ul style="list-style-type: none"> • ammonium chloride • ammonium bicarbonate • ammonium carbonate <i>(Entry 2 of 2)</i>	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.
9	Anise oil	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations containing more than 50% of anise oil; and • packed in containers having a nominal capacity of 50 mL or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
10	<p>Antihistamines (Entry 1 of 5) including:</p> <ul style="list-style-type: none"> • Alimemazine (trimeprazine) • Brompheniramine • Chlorphenamine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Pheniramine • Promethazine • Triprolidine <p>when NOT separately specified in this table</p>	<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. • <i>(for alimemazine and promethazine only)</i> If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
11	<p>Antihistamines (Entry 2 of 5) including:</p> <ul style="list-style-type: none"> • Alimemazine (trimeprazine) • Brompheniramine • Chlorphenamine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Pheniramine • Promethazine • Triprolidine <p>when NOT separately specified in this table</p>	<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. • <i>(for alimemazine and promethazine only)</i> If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
12	<p>Antihistamines (Entry 3 of 5) including:</p> <ul style="list-style-type: none"> • Brompheniramine • Chlorphenamine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Pheniramine • Promethazine • Triprolidine <p>when NOT separately specified in this table</p>	<p>In oral preparations indicated for COUGH, COLD OR FLU:</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 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. • <i>(for promethazine only)</i> If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
13	<p>Antihistamines (Entry 4 of 5) including:</p> <ul style="list-style-type: none"> • Brompheniramine • Chlorphenamine • Dexchlorpheniramine • Diphenhydramine • Doxylamine • Pheniramine • Promethazine • Triprolidine <p>when NOT separately specified in this table</p>	<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. • <i>(for promethazine only)</i> If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
14	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. • If breastfeeding, consult a doctor or pharmacist before use. • <i>(for promethazine only)</i> If pregnant or likely to become pregnant, consult a doctor or pharmacist before use. • Do not take this medicine for more than a few days. • This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.
15	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).

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
16	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
17	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
18	Aspirin (Entry 3 of 3)	When included in a schedule to the current Poisons Standard 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.
19	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 2 days of treatment, seek medical advice as soon as possible.
20	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 2 days of treatment, seek medical advice as soon as possible.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
21	<i>Azadirachta indica</i> (neem) (Entry 1 of 2)	For the purpose of exclusion from the schedules to the current Poisons Standard 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.
22	<i>Azadirachta indica</i> including its extracts and derivatives (Entry 2 of 2)	When included in Schedule 6 to the current Poisons Standard	<ul style="list-style-type: none"> • Do not use if pregnant or likely to become pregnant.
23	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.
24	Basil oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations or oils containing more than 5% of methyl chavicol; and • packed in containers having a nominal capacity of 25 mL or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
25	Bay oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25% of bay oil; and • packed in containers having: <ul style="list-style-type: none"> - a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or - a nominal capacity of 25 mL 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.
26	Benzocaine (Entry 1 of 4)	In dermal preparations containing MORE than 2% 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.
27	Benzocaine (Entry 2 of 4)	In dermal preparations containing 2% 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.
28	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
29	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.
30	Benzoyl peroxide	In Schedule 2 to the current Poisons Standard	<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.
31	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.
32	Bergamot oil	For the purpose of exclusion from the schedules to the current Poisons Standard; or when included in a schedule to the current Poisons Standard	<ul style="list-style-type: none"> Application to skin may increase sensitivity to sunlight.
33	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
34	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. 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.
35	Brompheniramine (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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
36	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.
37	Brompheniramine (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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
38	Brompheniramine (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.
39	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 [Insert number of days as per approved Product Information] days. • See a doctor if problem returns.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
40	Cajuput oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations or oils containing more than 25% of cajuput oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or – a nominal capacity of 25 mL 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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
41	Camphor (Entry 1 of 3)	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> included as a natural component in essential oils containing greater than 2.5% of camphor but 10% or less of camphor; and packed in containers having a nominal capacity of 25 mL 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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
42	Camphor (Entry 2 of 3)	For the purpose of exclusion from the schedules to the current Poisons Standard when: <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 mL or less, fitted with a restricted flow insert; or a nominal capacity of 25 mL 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.
43	Camphor (Entry 3 of 3)	When: <ul style="list-style-type: none"> included in a schedule to the current Poisons Standard, 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"> either <ul style="list-style-type: none"> READ SAFETY DIRECTIONS. [f] or <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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
44	Cassia oil	When included in a schedule to the current Poisons Standard	<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]
45	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.
46	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.
47	<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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
48	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.
49	Chlorhexidine (Entry 1 of 2)	In preparations for topical use on mucosal surfaces. <i>Note: If also for dermal use, Entry 2 below applies.</i>	<ul style="list-style-type: none"> • Avoid contact with eyes. • If in eyes, rinse well with water. • Chlorhexidine can cause severe allergic reactions. Seek immediate medical assistance if this occurs.
50	Chlorhexidine (Entry 2 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> • Avoid contact with eyes. • If in eyes, rinse well with water. • Mild skin irritation may occur; stop use if it becomes more severe. • Chlorhexidine can cause severe allergic reactions. Seek immediate medical assistance if this occurs.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
51	Chlorphenamine (Entry 1 of 4)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	<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.
52	Chlorphenamine (Entry 2 of 4)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	<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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
53	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.
54	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.
55	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
56	Cimetidine	In Schedule 3 to the current Poisons Standard	<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 2 weeks, consult a doctor.
57	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.
58	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
59	Cineole	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> in preparations or oils containing more than 25% 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 mL or less, fitted with a restricted flow insert; or a nominal capacity of 25 mL 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.
60	Cinnamon bark oil	When included in a schedule to the current Poisons Standard	<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 <ul style="list-style-type: none"> Avoid contact with skin. DO NOT SWALLOW. [g]

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
61	Cinnamon leaf oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25% of cinnamon leaf oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or – a nominal capacity of 25 mL 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.
62	<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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
63	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.
64	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
65	Clove oil (Entry 1 of 2)	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations containing more than 25% of clove oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or – a nominal capacity of 25 mL 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.
66	Clove oil (Entry 2 of 2)	When included in a schedule to the current Poisons Standard	<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]
67	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
68	<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 2 days of treatment, seek medical advice as soon as possible.
69	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.
70	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"> <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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
71	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.
72	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
73	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. • 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.
74	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.
75	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.
76	Dibromopropamidine	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
77	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
78	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
79	Diclofenac (Entry 3 of 3)	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.
80	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.
81	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.
82	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
83	Diphenhydramine (Entry 1 of 5)	In oral medicines that include dosage instructions for adults and children aged from 'x' years (where 'x' must not be less than 2) when NOT separately specified in this table	<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.
84	Diphenhydramine (Entry 2 of 5)	In oral medicines that ONLY include dosage instructions for CHILDREN aged between 'x' and 'y' years (where 'x' must not be less than 2, and 'y' must not be more than 11) when NOT separately specified in this table	<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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
85	Diphenhydramine (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.
86	Diphenhydramine (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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
87	Diphenhydramine (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: 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. • 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.
88	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 2 days of treatment, seek medical advice as soon as possible. • Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
89	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.
90	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
91	Doxylamine (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.
92	Doxylamine (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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
93	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. • 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.
94	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
95	Eletriptan	In divided oral preparations for relief of migraine	<ul style="list-style-type: none"> • Do not use: <ul style="list-style-type: none"> - without a previous diagnosis of migraine by a doctor - if you have heart disease, peripheral vascular disease (a blood vessel disorder) or high blood pressure or have previously had a heart attack or stroke. • Consult your doctor or pharmacist before use: <ul style="list-style-type: none"> - if you think you may be at risk of heart disease (including if you are post-menopausal or a male over the age of 40) - if you have liver or kidney problems or any other medical conditions - if you are taking any other medicines, including for migraine, depression or anxiety - if you are pregnant or breastfeeding. • Speak to a doctor or pharmacist if your migraine attacks become more frequent. Overuse of this medicine may worsen your condition. • This medicine may cause drowsiness. If affected, do not drive a vehicle or operate machinery.
96	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 2 weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
97	Eucalyptus oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25% of eucalyptus oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or – a nominal capacity of 25 mL 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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
98	Eugenol (Entry 1 of 2)	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations containing more than 25% of eugenol; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or – a nominal capacity of 25 mL 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.
99	Eugenol (Entry 2 of 2)	When included in a schedule to the current Poisons Standard	<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]

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
100	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.
101	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 2 weeks, consult a doctor.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
102	Fennel oil	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations or oils containing more than 5% of methyl chavicol; and • packed in containers having a nominal capacity of 25 mL or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
103	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.
104	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 [Insert number of days as per approved Product Information] days. • See a doctor if problem returns.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
105	Fluorides (Entry 1 of 3)	For the purpose of exclusion from the schedules to the current Poisons Standard when: <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 mg 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.
106	Fluorides (Entry 2 of 3)	When included in a schedule to the current Poisons Standard 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.
107	Fluorides (Entry 3 of 3)	In Schedule 2 to the current Poisons Standard 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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
108	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
109	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.
110	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
111	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.
112	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.
113	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.
114	Hexachlorophane	In preparations for skin cleansing purposes containing 3% or less of hexachlorophane.	<ul style="list-style-type: none"> • For external washing only. • Rinse skin thoroughly after use.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
115	Hydrocortisone (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> • <i>either</i> <ul style="list-style-type: none"> - Do not use for children under 2 years old unless a doctor has told you to. • <i>or (if Schedule 2 or 3 to the current Poisons Standard excludes use in children under 12 years of age)</i> <ul style="list-style-type: none"> - Do not use for children under 12 years of age. • 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.
116	Hydrocortisone (Entry 2 of 2)	In preparations for topical rectal use	<ul style="list-style-type: none"> • 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.
117	Hydrogen peroxide (Entry 1 of 3)	In concentrations of more than 3% up to 10%	<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]

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
118	Hydrogen peroxide (Entry 2 of 3)	In concentrations of more than 10% up to 20%	<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.
119	Hydrogen peroxide (Entry 3 of 3)	In concentrations of more than 20%	<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.
120	Hydroquinone	In Schedule 2 to the current Poisons Standard	<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 3 months, seek doctor's advice. • Do not exceed recommended dose. Excessive or prolonged use should be avoided because darkening of the skin can occur.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
121	Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna (Entry 1 of 3)	Where the MRDD contains MORE than 10 mg 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.
122	Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna (Entry 2 of 3)	Where the MRDD contains MORE than 10 mg 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>].
123	Hydroxyanthracene derivatives such as those from: <ul style="list-style-type: none"> • Aloe • Buckthorn • Cascara • Frangula • Rhubarb • Senna (Entry 3 of 3)	Where the MRDD contains 10 mg 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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
124	8-Hydroxyquinoline (including salts and derivatives)	In preparations for internal use	<ul style="list-style-type: none"> Do not take for periods longer than 4 weeks except on medical advice.
125	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 2 days of treatment, seek medical advice as soon as possible.
126	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 2 days of treatment, seek medical advice as soon as possible. Do not use during pregnancy or breastfeeding unless advised by your doctor or pharmacist.
127	<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 2 days of treatment, seek medical advice as soon as possible.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
128	Ibuprofen (Entry 1 of 6)	For the purpose of exclusion from the schedules to the current Poisons Standard, 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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
129	Ibuprofen (Entry 2 of 6)	When included in a schedule to the current Poisons Standard 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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
130	Ibuprofen (Entry 3 of 6)	For the purpose of exclusion from the schedules to the current Poisons Standard, 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. • Do not use in children 6 years of age or less.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
131	Ibuprofen (Entry 4 of 6)	When included in a schedule to the current Poisons Standard 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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
132	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
133	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.
134	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.
135	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.
136	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.
137	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
138	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.
139	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
140	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
141	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
142	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.
143	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.
144	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 2 weeks of completing the course, consult a doctor. Ask your doctor or pharmacist before use if you are taking other medicines regularly.
145	Lemon oil	For the purpose of exclusion from the schedules to the current Poisons Standard	<ul style="list-style-type: none"> Application to skin may increase sensitivity to sunlight.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
146	<i>Leptospermum scoparium</i> oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25% of <i>Leptospermum scoparium</i> oil; and • packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or – a nominal capacity of 25 mL 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.
147	Levocabastine (Entry 1 of 2)	In eye or nasal preparations containing 0.5 mg/mL or less of levocabastine	<ul style="list-style-type: none"> • Do not use if pregnant.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
148	Levocabastine (Entry 2 of 2)	In eye or nasal preparations containing MORE THAN 0.5 mg per mL 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.
149	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.
150	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.
151	Lidocaine (Lignocaine) (Entry 1 of 4)	In dermal preparations containing MORE THAN 2% 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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
152	Lidocaine (Lignocaine) (Entry 2 of 4)	In dermal preparations containing 2% 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.
153	Lidocaine (Lignocaine) (Entry 3 of 4)	In preparations for topical oral use containing more than 1.5% lidocaine.	<ul style="list-style-type: none"> • Do not use for teething pain in children.
154	Lidocaine (Lignocaine) (Entry 4 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.
155	Lime oil	For the purpose of exclusion from the schedules to the current Poisons Standard	<ul style="list-style-type: none"> • Application to skin may increase sensitivity to sunlight.
156	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
157	Loperamide hydrochloride	In medicines for oral use	<ul style="list-style-type: none"> • If the condition persists after 2 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.
158	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.
159	Marjoram oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations containing more than 50% of marjoram oil; and • packed in containers having a nominal capacity of 50 mL or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
160	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
161	Melaleuca oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations containing more than 25% of melaleuca oil; and • when packed in containers having: <ul style="list-style-type: none"> – a nominal capacity of 15 mL or less, fitted with a restricted flow insert; or – a nominal capacity of 25 mL 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.

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Item	Substances	Circumstances	Required Statements
162	Melatonin	In modified-release tablets containing 2 mg or less of melatonin	<ul style="list-style-type: none"> • Do not use if: <ul style="list-style-type: none"> - you are under 55 years of age - you are taking any other medicines for sleep - you have liver problems - you are pregnant or breastfeeding. • Unless a doctor has told you to, do not use: <ul style="list-style-type: none"> - for more than 3 weeks - if you have kidney problems - if you have an autoimmune disease. • Consult a pharmacist or doctor before use if you are taking other medicines regularly. • Do not drink alcohol while taking this medicine. • This medication may cause drowsiness. If affected do not drive or operate machinery.
163	Menthol (Entry 1 of 5)	In dermal preparations containing 1% or less, EXCEPT patches	<ul style="list-style-type: none"> • Avoid contact with eyes.
164	Menthol (Entry 2 of 5)	In dermal preparations containing more than 1% and up to 5%, EXCEPT patches	<ul style="list-style-type: none"> • Avoid contact with eyes. • If you have sensitive skin, test this product on a small area of skin before applying it to a large area. • If irritation develops, discontinue use.
165	Menthol (Entry 3 of 5)	In dermal preparations containing more than 5%, EXCEPT patches	<ul style="list-style-type: none"> • Avoid contact with eyes. • Contains a high concentration of menthol, which can cause severe skin irritation. • If you have sensitive skin, test this product on a small area of skin before applying it to a large area. • If irritation develops, discontinue use.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
166	Menthol (Entry 4 of 5)	In dermal patches containing more than 1% and up to 5%	<ul style="list-style-type: none"> • If irritation develops, discontinue use.
167	Menthol (Entry 5 of 5)	In dermal patches containing more than 5%	<ul style="list-style-type: none"> • Contains a high concentration of menthol, which can cause severe skin irritation. • If irritation develops, discontinue use.
168	Methyl salicylate (Entry 1 of 2)	In dermal preparations containing 1% or less of methyl salicylate	<ul style="list-style-type: none"> • Do not use if pregnant or likely to become pregnant. • Do not use in children 6 years of age or less. • Application to skin may increase sensitivity to sunlight. • Avoid prolonged exposure in the sun.
169	Methyl salicylate (Entry 2 of 2)	In dermal preparations containing more than 1% of methyl salicylate	<ul style="list-style-type: none"> • Do not use if pregnant or likely to become pregnant. • Do not use in children 6 years of age or less. • Application to skin may increase sensitivity to sunlight. • Avoid prolonged exposure in the sun. • If irritation develops, discontinue use.
170	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)].
171	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.

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Item	Substances	Circumstances	Required Statements
172	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 [Insert number of days as per approved Product Information] days. • See a doctor if problem returns.
173	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.
174	Mometasone (Entry 1 of 2)	In preparations for dermal use	<ul style="list-style-type: none"> • Do not use: <ul style="list-style-type: none"> - in or around the eyes - for acne - on broken skin or skin infections (e.g. cold sores, shingles, thrush, tinea) - if you are sensitive to any corticosteroids. • Unless a doctor has told you to, do not use: <ul style="list-style-type: none"> - on the face, large areas of the skin, or areas that rub together - under a bandage, dressing, nappies or plastic pants - for more than 7 days - if you are pregnant or breastfeeding - for children under 12 years old. • If irritation occurs, discontinue use and seek medical advice. • Seek medical advice if there is no improvement in symptoms after using for 1 week.

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Item	Substances	Circumstances	Required Statements
175	Mometasone (Entry 2 of 2)	In nasal spray preparations	<ul style="list-style-type: none"> • Do not exceed the maximum stated dose. • Do not use for more than 6 months without the advice of your doctor or pharmacist. • See your doctor or pharmacist before using this product if: <ul style="list-style-type: none"> - you have a nasal or sinus infection - you have recently had an injury or surgery to your nose - you have ulceration in your nose - you are pregnant or breastfeeding. • See your doctor or pharmacist if: <ul style="list-style-type: none"> - symptoms are not relieved within 7 days - your nose bleeds - you develop signs or symptoms of a nasal or sinus infection such as fever, pain or swelling, or discoloured nasal discharge - you have eye pain or visual disturbances.
176	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
177	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
178	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
179	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.

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Item	Substances	Circumstances	Required Statements
180	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
181	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 2 weeks, consult a doctor.
182	Nutmeg oil	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations containing more than 50% of nutmeg oil; and • packed in containers having a nominal capacity of 25 mL or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
183	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 [insert number of days as per approved Product Information] days. • See a doctor if no better after [Insert number of days as per approved Product Information] days. • See a doctor if problem returns.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
184	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 2 weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.
185	Orange oil (bitter)	For the purpose of exclusion from the schedules to the current Poisons Standard	<ul style="list-style-type: none"> • Application to skin may increase sensitivity to sunlight.
186	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
187	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.
188	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 3 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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
189	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 3 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.
190	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 2 weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
191	Paracetamol (Entry 1 of 3)	For the purpose of exclusion from the schedules to the current Poisons Standard	<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.
192	Paracetamol (Entry 2 of 3)	In Schedule 2 or 3 to the current Poisons Standard	<ul style="list-style-type: none"> • <i>either or both</i> <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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
193	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
194	Pennyroyal oil	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations containing more than 4% of d-pulegone; and • when packed in containers having a nominal capacity of 15 mL 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.
195	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.
196	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
197	Permanganates (see also Potassium permanganate)	When included in Schedule 6 to the current Poisons Standard	<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.
198	Pheniramine (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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
199	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.
200	Pheniramine (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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
201	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.
202	Phenol and any other homologue of phenol	When included in Schedule 2 to the current Poisons Standard	<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]
203	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
204	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
205	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.
206	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.
207	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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
208	Phenylephrine <i>Entry 6 of 7)</i>	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 3 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.
209	Phenylephrine <i>(Entry 7 of 7)</i>	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 3 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.
210	Pholcodine <i>(Entry 1 of 2)</i>	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
211	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.
212	<i>Piper methysticum</i>	For the purpose of exclusion from the schedules to the current Poisons Standard 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.
213	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.
214	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.
215	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
216	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.
217	Potassium permanganate	In Schedule 6 to the current Poisons Standard	<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.
218	Povidone-iodine	In preparations for dermal use	<ul style="list-style-type: none"> • If skin irritation or rash occurs, discontinue use immediately.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
219	Promethazine (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. • If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
220	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. • If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
221	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. • If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.
222	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. • If pregnant or likely to become pregnant, consult a doctor or pharmacist before use.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
223	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>(Note: Promethazine medicines indicated for sedation that only include dosage instructions for children aged < 12 years are subject to 'Promethazine (Entry 2 of 5))</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 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.
224	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.
225	<p>Proton pump inhibitors including:</p> <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 2 weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
226	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.
227	Pseudoephedrine (Entry 2 of 3)	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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
228	Pseudoephedrine (Entry 3 of 3)	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.
229	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.
230	Pyridoxal (see also Vitamin B6, Vitamins) (Entry 1 of 2)	In SINGLE-INGREDIENT preparations containing 200 mg or less but more than 50 mg 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.
231	Pyridoxal (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI-INGREDIENT preparations containing 200 mg or less but more than 50 mg 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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
232	Pyridoxine (see also Vitamin B6, Vitamins) (Entry 1 of 2)	In SINGLE- INGREDIENT preparations containing 200 mg or less but more than 50 mg 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.
233	Pyridoxine (see also Vitamin B6, Vitamins) (Entry 2 of 2)	In MULTI- INGREDIENT preparations containing 200 mg or less but more than 50 mg 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.
234	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.
235	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 2 weeks of completing the course, consult a doctor. • Ask your doctor or pharmacist before use if you are taking other medicines regularly.
236	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 2 weeks, consult a doctor.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
237	Rizatriptan	In divided oral preparations for relief of migraine	<ul style="list-style-type: none"> • Do not use: <ul style="list-style-type: none"> - without a previous diagnosis of migraine by a doctor - if you have heart disease, peripheral vascular disease (a blood vessel disorder) or high blood pressure or have previously had a heart attack or stroke. • Consult your doctor or pharmacist before use: <ul style="list-style-type: none"> - if you think you may be at risk of heart disease (including if you are post-menopausal or a male over the age of 40) - if you have liver or kidney problems or any other medical conditions - if you are taking other medicines for migraine - if you are taking, or have taken in the last 2 weeks, medicine for depression or anxiety - if you are pregnant or breastfeeding. • Speak to a doctor or pharmacist if your migraine attacks become more frequent. Overuse of this medicine may worsen your condition. • This medicine may cause drowsiness. If affected, do not drive a vehicle or operate machinery.
238	Safrole	When included in a schedule to the current Poisons Standard	<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.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
239	Sage oil	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations containing more than 4% of thujone; and • packed in containers having a nominal capacity of 15 mL 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.
240	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.
241	Sassafras oil	When included in a schedule to the current Poisons Standard	<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.
242	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
243	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.
244	Silver (see also Silver salts)	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> in chewing gum containing 5 mg or less of silver per dosage unit; or in solutions for oral use containing 0.3% or less of silver 	<ul style="list-style-type: none"> Overuse may stain skin or mouth.
245	Silver salts (see also Silver)	In smoking deterrents.	<ul style="list-style-type: none"> WARNING - Overuse may stain the skin or mouth.
246	Sodium fluoride (see also Fluorides)	In preparations for ingestion when in Schedule 2 to the current Poisons Standard	<ul style="list-style-type: none"> Use of this product is not necessary in areas supplied with fluoridated water.

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Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
247	Star anise oil	<p>For the purpose of exclusion from the schedules to the current Poisons Standard when:</p> <ul style="list-style-type: none"> • in preparations containing more than 50% of star anise oil; and • packed in containers having a nominal capacity of 50 mL or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
248	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
249	Sumatriptan	In divided oral preparations for relief of migraine	<ul style="list-style-type: none"> • Do not use: <ul style="list-style-type: none"> - without a previous diagnosis of migraine by a doctor - if you have heart disease, peripheral vascular disease (a blood vessel disorder) or high blood pressure or have previously had a heart attack or stroke. • Consult your doctor or pharmacist before use: <ul style="list-style-type: none"> - if you think you may be at risk of heart disease (including if you are post-menopausal or a male over the age of 40) - if you have liver or kidney problems or any other medical conditions - if you are taking other medicines for migraine - if you are taking, or have taken in the last 2 weeks, medicine for depression or anxiety - if you are pregnant or breastfeeding. • Speak to a doctor or pharmacist if your migraine attacks become more frequent. Overuse of this medicine may worsen your condition. • This medicine may cause drowsiness. If affected, do not drive a vehicle or operate machinery.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
250	<i>Symphytum</i> spp	In Schedule 5 to the current Poisons Standard	<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]
251	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.
252	Tetracaine (amethocaine) (Entry 1 of 2)	When included in Schedule 2 to the current Poisons Standard 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.
253	Tetracaine (amethocaine) (Entry 2 of 2)	For the purpose of exclusion from the schedules to the current Poisons Standard when in dermal preparations containing 2% 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.
254	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
255	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.
256	Thyme oil	For the purpose of exclusion from the schedules to the current Poisons Standard when: <ul style="list-style-type: none"> • in preparations containing more than 50% of thyme oil; and • packed in containers having a nominal capacity of 25 mL or less, fitted with a restricted flow insert 	<ul style="list-style-type: none"> • KEEP OUT OF REACH OF CHILDREN.
257	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 [Insert number of days as per approved Product Information] days. • See a doctor if problem returns.
258	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
259	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.
260	Triamcinolone	In topical preparations for the treatment of mouth ulcers	<p><i>either</i></p> <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. <p><i>or</i></p> <ul style="list-style-type: none"> • If symptoms persist beyond 5 days consult a [doctor / doctor or dentist].
261	Triprolidine (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. <p><i>or</i></p> <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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
262	Tripolidine (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.
263	Tripolidine (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.

Required Advisory Statements for Medicine Labels

Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
264	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.
265	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
266	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.
267	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.
268	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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
269	Vitamin A (See also <i>Vitamins</i>)	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]
270	Vitamin B6 <ul style="list-style-type: none"> • pyridoxal • pyridoxine (Entry 1 of 2) (See also <i>Vitamins</i>)	In SINGLE-INGREDIENT preparations containing 200 mg or less but more than 50 mg 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.
271	Vitamin B6 <ul style="list-style-type: none"> • pyridoxal • pyridoxine (Entry 2 of 2) (See also <i>Vitamins</i>)	In MULTI-INGREDIENT preparations containing 200 mg or less but more than 50 mg 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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
272	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 3 days at a time unless advised by a doctor or pharmacist. • Frequent or prolonged use may cause nasal congestion to recur or worsen.
273	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.
274	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 3 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.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
275	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 3 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.
276	Zinc compounds	In preparations for internal use with a recommended daily dose of more than 25 mg of zinc	<i>either</i> <ul style="list-style-type: none"> • WARNING - This medication may be dangerous when used in large amounts or for a long period. <i>or</i> <ul style="list-style-type: none"> • WARNING – Contains zinc, which may be dangerous when used in large amounts or for a long period.

Required Advisory Statements for Medicine Labels			
Column 1	Column 2	Column 3	Column 4
Item	Substances	Circumstances	Required Statements
277	Zolmitriptan	In divided oral preparations for relief of migraine	<ul style="list-style-type: none"> • Do not use: <ul style="list-style-type: none"> - without a previous diagnosis of migraine by a doctor - if you have heart disease, peripheral vascular disease (a blood vessel disorder) or high blood pressure or have previously had a heart attack or stroke. • Consult your doctor or pharmacist before use: <ul style="list-style-type: none"> - if you think you may be at risk of heart disease (including if you are post-menopausal or a male over the age of 40) - if you have liver or kidney problems or any other medical conditions - if you are taking other medicines for migraine - if you are taking, or have taken in the last 2 weeks, medicine for depression or anxiety - if you are pregnant or breastfeeding. • Speak to a doctor or pharmacist if your migraine attacks become more frequent. Overuse of this medicine may worsen your condition. • This medicine may cause drowsiness. If affected, do not drive a vehicle or operate machinery.