



Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guideline for over-the-counter medicines

Appendix 5: Guidelines on OTC application for specific substances

Version 1.0, October 2012

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

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Version history

Version	Description of change	Author	Effective date
V1.0	Update of ARGOM Chapter 9 MEC Guidelines. Re-formatting of Chapter 9 as Appendix 5 – Guideline on OTC applications for specific substances.	MAG – OTCME	October 2012

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Introduction

This guidance document is intended to assist sponsors in submitting acceptable applications for registration of over-the-counter (OTC) medicines.

Products are assessed according to the best clinical and scientific information at the time of evaluation. If a sponsor believes that a particular application warrants a departure from the guidelines, a justification should be submitted with the application.

Sponsors of products that were approved before the introduction of a new guideline should bring the product into compliance with the guideline at the earliest opportunity, for example, when any changes are proposed to the product labelling.

Sponsors should also refer to the *Required Advisory Statements for Medicine Labels* (RASML)¹.



Note: This guidance document contains references to warning statements that are being included in the current updating of the RASML document. Warning statements marked with an (*) which are included in the updated version of the RASML document will be removed from this guidance document once the updated RASML is implemented.

Allantoin

Claims for the efficacy of allantoin as a wound healing agent will not be accepted, unless evidence is provided to justify these claims.

Alpha hydroxy acids

There is evidence to suggest that the use of topical products containing alpha hydroxy acids (such as glycolic acid, lactic acid, citric acid and other fruit acids) may make users more sensitive to sunlight and especially to the ultraviolet (UV) radiation component of sunlight. UV exposure can damage the skin and at high doses, especially over a long period, can cause skin cancer.

Therefore the labels of products containing alpha hydroxy acids as active ingredients should advise that the product may make the skin more sensitive to sunlight and to take appropriate protection measures against sun exposure. In addition, these products are not recommended for use on children and infants.

The following statements should be included in the labelling of products containing alpha hydroxy acids:

- **This product may make your skin more sensitive to sunlight;*
- **Sun exposure should be limited by using a sunscreen and by wearing protective clothing;*

¹ <http://www.gov.au/industry/labelling-rasml.htm>

- **If you have sensitive skin, test this product on a small area of skin before applying it to a large area;*
- **Transient stinging or irritation may occur when using this product. If irritation persists, discontinue use; and*
- **Not recommended for use on children or infants.*

Anaesthetic lozenges

The labels of lozenges containing a local anaesthetic agent should include a label warning statement such as:

- **Do not take hot food or drink soon after using this product because it may burn your mouth.*

Where indicated for use in children, the labels of lozenges containing a local anaesthetic agent should also include a label warning statement such as:

- **Do not give to children under six years of age, unless recommended by a doctor, pharmacist or dental professional.*

Anaesthetics, dermal

The labels of all products containing local anaesthetics for dermal use must contain a statement such as:

- **If irritation occurs, stop use immediately and seek medical advice.*

In addition, if the product contains:

- cinchocaine for topical use

or

- concentration of 2% or greater of total local anaesthetic substances (e.g. amethocaine, benzocaine and lignocaine)

the labels must also contain a statement such as:

- **Do not apply to large areas of the body except on the advice of a healthcare practitioner.*

See also '[Nappy rash](#)' and '[Vaginal itch, topical preparations](#)'

Antacids, liquid

Liquid antacids are susceptible to microbiological contamination and deterioration of flavour and fragrance after the container is opened. Experience also indicates that some patients, contrary to the sponsor's advice, drink liquid antacids directly from the bottle. Where liquid antacids do not comply with the criteria as set out in *ARGOM Appendix 2*

Guidelines on quality aspects of OTC application: Section 10 Microbiological testing², throughout the life of the product in both opened and unopened containers (i.e. on the basis of 'in use' stability data), the label should include a statement advising consumers to discard the contents 3 months after opening the bottle. Consumers will be assisted if a space is provided for the user to write the date of first opening.

Anthelmintics

The most commonly occurring worms in Australia are threadworms. Other types of worms (e.g. roundworm, hookworm, whipworm and tapeworm) occur less commonly.

The product labels should not encourage the regular use of anthelmintics. In addition, the product labels or a package insert should contain statements such as:

- *A common symptom of threadworm infestation is itching around the anus and vagina, which may result in restless sleep and irritability.*
- *Evidence of infestation should be present before treating for threadworm.*
- *If a family member has threadworms, then each member of the family should be treated.*
- *If symptoms persist, see your doctor.*

Mebendazole

The label indications for products containing mebendazole may include treatment of threadworm and other types of worms (e.g. roundworm, hookworm, whipworm, and tapeworm).

As consumers are unlikely to be able to differentiate between worm types, and the recommended dosage of mebendazole for the treatment of threadworm and other types of worms differs, the labels for products containing mebendazole should only include directions for use in the treatment of threadworm.

The recommended dosage of mebendazole for treatment of threadworms in adults and children aged 2 years and over is 100 mg as a single dose.

If the indications on the product labels include use for other, less commonly occurring types of worms (in addition to use for threadworms), the labels should not include directions for use of mebendazole for the treatment of worms other than threadworms. However, the directions for use on the labels could include a statement such as:

- *Roundworm, hookworm and whipworm rarely occur in the general Australian population. If suspected, medical advice should be sought.*

Sponsors may include dosage instructions for treatment of worms other than threadworms in a product information document. The recommended dosage of mebendazole for treatment of worms other than threadworms in adults and children aged 2 years and over is 100 mg twice a day for three days. Where this information is included in the Product Information (PI) and a Consumer Medicine Information (CMI) document and/or package insert is supplied, the CMI and/or package insert should include a statement such as:

² <http://www.tga.gov.au/industry/otc-argom-app2.htm>

- *Medical advice should be sought before use of the product for worms other than threadworms.*

Antifungal agents

Topical use

Prophylactic use of topical antifungal agents, including application to shoes or clothing, should be justified.

Because fungal infections may recur if treatment is stopped as soon as symptoms disappear, product labels should state that the product should be applied for 14 days after symptoms disappear. This is not required on the labels of topical products containing terbinafine, or for other products where the sponsor can justify its omission.

In some circumstances, such as communal showers and tropical climates, more frequent use of a topical antifungal agent may be appropriate, but the directions for use should set out the relevant circumstances.

Topical oral mucosal application - miconazole

Some azole antifungal agents (miconazole and fluconazole, in particular) may increase international normalised ratio (INR, a measure of blood clotting) levels in patients who are taking warfarin or other anticoagulants [due to inhibition of Cytochrome P450 2C9 (CYP2C9), which metabolises (S)-warfarin]].

The PI for OTC topical products for oral mucosal application containing miconazole should state that miconazole has been shown to increase INR levels in patients taking warfarin, as inhibition of CYP2C9 by miconazole reduces the metabolism of warfarin. Therefore, these patients may be at risk of increased bleeding or bruising. Consistent information should be included in the CMI for these products.

The labels or package inserts of OTC topical products for oral mucosal application containing miconazole should include a statement advising people who are taking warfarin or other anticoagulants to ask their doctor or pharmacist before using the product, because bleeding or bruising may occur.

Use for vaginal candidiasis

Unless otherwise justified, the labels or package inserts of topical antifungal agents for vaginal use should include advice that the use of condoms or diaphragms for contraception is not recommended during treatment (as some excipients in many vaginal cream or pessary formulations may damage the integrity of the condom or diaphragm).

The PI for OTC vaginal products containing miconazole and OTC oral fluconazole products for vaginal thrush should state that the active ingredient (miconazole or fluconazole) has been shown to increase INR levels in patients taking warfarin, as inhibition of CYP2C9 by the active ingredient (miconazole or fluconazole) reduces the metabolism of warfarin.

Therefore, these patients may be at risk of increased bleeding or bruising. Consistent information should be included in the CMI for these products.

The labels or package inserts of OTC vaginal products containing miconazole and OTC oral fluconazole products for vaginal thrush should include a statement advising people who are taking warfarin or other anticoagulants to ask their doctor or pharmacist before using the product, because bleeding or bruising may occur.

No data are available on whether this interaction may also occur with OTC vaginal products containing butoconazole. In the absence of data indicating that this interaction will not occur following vaginal administration of butoconazole, the PI should include advice such as the following (under the subheading, 'Interactions with other medicines', or similar):

- *Studies have not been conducted to evaluate the potential for interactions between butoconazole and coumarin anticoagulants, such as warfarin. However, some azole antifungal agents, such as miconazole and fluconazole, have been shown to increase INR levels in patients taking warfarin, due to inhibition of CYP2C9 and reduced metabolism of warfarin. Therefore, caution is advised in patients taking coumarin anticoagulants, as butoconazole may increase INR, and these patients may be at risk of increased bleeding or bruising.*

The CMI for OTC vaginal products containing butoconazole should include a statement that people who are taking warfarin or other anticoagulants should ask a doctor or pharmacist before using the product, because bleeding or bruising may occur. Advice that no interactions have been reported with the product could also be included in the CMI. The product labels or package insert should also include this information.

Antihistamines

Use in respiratory tract infections

Clinical data must be provided to justify claims for the use of antihistamines for lower respiratory tract conditions (including infections and asthma).

Use as hypnotics

Antihistamines (H1 receptor antagonists), especially ethanolamines (e.g. doxylamine, diphenhydramine) and phenothiazines (e.g. promethazine), have hypnotic properties. In general, sleep disorders should be medically assessed, as they may be symptomatic of more serious conditions such as depressive illness. The use of non-medically prescribed hypnotics is therefore not encouraged, and OTC products will not be registered for long-term use in insomnia.

In the case of products containing antihistamines with hypnotic properties that are indicated for short-term use in occasional insomnia:

- the pack size should be limited to not more than 10 doses;

- the CMI, package insert or label should include the following principles of good sleep hygiene:
 - go to bed and arise at the same time daily
 - engage in relaxing activities before bedtime
 - exercise regularly but not in the late evening
 - avoid eating meals or large snacks just before bedtime
 - eliminate daytime naps
 - avoid caffeine-containing drinks after midday
 - avoid alcohol or the use of nicotine late in the evening
 - minimise external disruption (e.g. light and noise)
 - if you are unable to sleep, do not become anxious; leave the bedroom and participate in relaxing activities such as reading or listening to music until you are tired.

In addition, the labels of these products should include the following statements:

- **Not recommended for use by pregnant or lactating women.*
- **This product should be taken on medical or pharmacist advice.*
- **This product is for temporary use.*
- **This preparation is to aid sleep. Drowsiness may continue the following day. If affected do not drive or operate machinery. Avoid alcohol.*

The requirements relating to the pack size and principles of good sleep hygiene need not be applied to antihistamine products with indications for short-term use for sedation that are primarily intended for paediatric use.

See also '[Paediatric products - paediatric products containing antihistamines](#)', '[Soft gel capsules for sedation](#)'

Antimicrobial sore throat treatments

See '[Sore throat treatments – antimicrobial](#)'

Aspartame

Aspartame is a sweetening agent based on the essential amino acid phenylalanine which is normally metabolised to tyrosine. The enzyme required for this metabolism is lacking in people with phenylketonuria. Aspartame is included in the First Schedule of the Therapeutic Goods Order No. 69 (TGO 69) *General requirements for labels for medicines*³.

Medicines containing aspartame or phenylalanine should include the following warning statement:

- **Phenylketonurics are warned that this product contains aspartame (phenylalanine).*

³ <http://www.tga.gov.au/industry/legislation-tgo.htm>

Aspirin

Indications

Analgesia

Sponsors may use indications consistent with any or all of the representative indications set out below, as appropriate to a particular product, without the need to supply supporting efficacy data:

- For the temporary relief of pain (and discomfort) and/or inflammation associated with:
 - headache
 - migraine headache
 - tension headache
 - sinus pain
 - toothache
 - dental procedures
 - backache
 - muscular aches and pains
 - arthritis
 - osteoarthritis
 - rheumatic pain
 - menstruation/period pain
 - fibrositis
 - neuralgia
 - sore throat
 - tennis elbow
 - colds and flu
 -
- Reduces fever and/or the discomfort associated with fever.

Sponsors may propose other indications but should contact the TGA for advice on whether data will be required to support the safety and efficacy of the product for those indications.

Combination OTC analgesic products that contain aspirin and codeine may include claims of 'strong' or 'powerful' pain relief (or similar). These claims will not be accepted for products that contain aspirin as the only analgesic agent, or aspirin in combination with another analgesic agent, unless the claims are justified on the basis of clinical efficacy data.

As fever is a normal and generally beneficial response to infection, no elaboration to the words "*reduces fever*" will be accepted except in the context of limits to the duration of treatment, relief of discomfort associated with fever or examples of conditions where fever may occur.

Antiplatelet activity

For aspirin products that are indicated for reduction of the risk of heart attack and stroke in patients with known cardiovascular or cerebrovascular disease and inhibition of platelet aggregation, the ARTG indications should be consistent with the following:

- *For the treatment of patients with known cardiovascular or cerebrovascular disease, as an antiplatelet agent for prophylaxis against acute myocardial infarction, unstable angina, transient ischaemic attack and cerebrovascular accident (stroke).*

Where there is a PI document, the 'Indications' section should be consistent with ARTG indications.

An exemption is required under Section 42DK of the *Therapeutic Goods Act 1989* (the Act) for the use of claims relating to the cardiovascular or cerebrovascular system or use as an antiplatelet agent on product labelling⁴.

Dose

Analgesia

Adult dosage recommendations (adults and children over 12 years):

- 300 mg to 1000 mg every four hours as necessary. Dosage should not exceed 4 g (expressed on the label as the number of units, e.g. tablets) in 24 hours. Products containing aspirin should not be taken for more than 10 days (except on medical advice).

The labels of products containing aspirin should not include dosage instructions for children aged 12 years and under.

Antiplatelet

Dosage instructions consistent with 75 - 325 mg aspirin once daily will not require clinical data or further justification.

The product labelling should clearly state that aspirin should only be used as an antiplatelet agent on the advice of a doctor.

Combination products

Products containing aspirin together with one or more other active ingredients, which are similar to existing registered products, will usually not require efficacy or safety data, provided they comply with the guideline on fixed dose combination products (see *ARGOM Appendix 1 – Guidelines on efficacy and safety aspects of OTC application: Section 9 Fixed dose combination products*⁵). Where new combinations are proposed (i.e. combinations and/or strengths that are not included in the ARTG for supply in Australia), the safety and efficacy of the combination will need to be justified.

Bath oils

Oily products intended for use in the bath may cause the bath to become slippery or, when used in a baby's bath, may cause the baby to become slippery. Products of this type should contain a label warning statement such as:

- *Caution: Use of this product may cause the body and bathroom surfaces to become slippery. Particular care should be exercised when handling a baby.*

⁴ <http://www.tga.gov.au/industry/advertising-forms-restricted-representation.htm>

⁵ <http://www.tga.gov.au/industry/otc-argom-app1.htm>

Benzocaine

See [‘Anaesthetics, dermal’](#)

Benzoyl peroxide

Labels of unscheduled products containing benzoyl peroxide should include the following statements:

- **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.*

Efficacy and safety data will not be required for:

- topical ‘leave-on’ products (e.g. topical creams or ointments) containing 2.5% to 10% benzoyl peroxide that are intended for treatment of acne; or
- topical wash products containing 2.5% to 10% benzoyl peroxide that are intended for treatment of mild to moderate acne, with directions for use advising contact times of at least 30 seconds.

Efficacy and safety data will be required for:

- indications or strengths other than those noted above; and/or
- topical wash products with contact times shorter than 30 seconds.

Bowel cleansing oral preparations – sodium salts

Severe dehydration and electrolyte disturbances may occur in ‘at risk’ patient groups (such as elderly people, and patients with impaired renal function, diabetes or heart conditions) following ingestion of oral products containing sodium phosphate or sodium picosulfate and intended for bowel cleansing purposes (e.g. prior to colonoscopy or other procedures).

The PI, CMI and/or other package insert, and labels of these products should include ‘boxed warnings’ consistent with the following:

- Product Information: *WARNING: Life threatening dehydration and/or electrolyte disturbances may occur in ‘at risk’ groups – see Contraindications and Precautions*
- CMI and/or package insert: *WARNING: Life threatening dehydration and/or electrolyte disturbances may occur in some people. Read the section with the heading ‘Before you take [this product]’*
- Labels: *WARNING: Life threatening dehydration and/or electrolyte disturbances may occur in some people. Read the enclosed leaflet before you take this product.*

The PI should advise that these products should not be used in patients with clinically significant renal impairment, and that the products should be used with caution in patients with impaired kidney function, diabetes, heart conditions or pre-existing electrolyte disturbances, patients taking other medicines that may affect electrolyte levels, and elderly or debilitated patients. Advice that adequate hydration is very important for safe and effective use of the product, and that medications such as diuretic may exacerbate volume depletion associated with bowel cleansing, should also be included in the product information.

The CMI, package insert and/or labels should advise elderly people, and people with impaired kidney function, diabetes or heart conditions, to discuss use of the product with their doctor prior to use. Patients should also be advised to discuss any other medicines they are taking with their doctor prior to the taking of the product.

Nephrocalcinosis and renal impairment may occur following use of oral sodium phosphate products in 'at risk' or inappropriate patient groups. The PI, CMI and/or other package insert of oral sodium phosphate products indicated for bowel cleansing should include warnings advising healthcare professionals and consumers that nephrocalcinosis and renal impairment may occur following use of these products.

Bronchitis, use of term

Bronchitis is an inflammation of the mucous membranes of the bronchi. The condition is serious and complications can be severe. Products which provide symptomatic relief should not include the word "bronchitis" as part of the product's name, and should not include the word "bronchitis" on the labels, other than in the context of a statement such as:

- *For the relief of cough of bronchitis. If the cough persists, seek medical advice.*

Burn treatment products

The label of these products should indicate that immediate treatment should consist of the rapid application of cold water or cold packs for at least 20 minutes and that the product should only be applied later. Ice should not be applied directly to the burnt area.

Directions for use should indicate clearly that the product is for the first-aid treatment of minor burns only and that medical advice should be sought for the treatment of more serious burns.

Caffeine

The dose for adults and children 12 years and over of preparations containing caffeine for use as a stimulant or alerting agent should be consistent with the following:

- 100 mg per dose maximum, which may be repeated at three hourly intervals. Do not exceed 600 mg in 24 hours.

Labels of products containing caffeine should advise users to limit their total caffeine intake from all sources (including tea, coffee or other products containing caffeine), and should provide information regarding the amount of caffeine per dose of the product relative to the caffeine content of a cup of coffee for example a statement such as the following should be included on the label:

- *Limit the use of caffeine-containing products (including tea and coffee) when taking this product. One tablet/capsule contains about the same amount of caffeine as x cups of instant coffee.*

The Food Standards Australia New Zealand (FSANZ) website states that a 250 mL cup of instant coffee (1 teaspoon/cup) contains 60-80 mg caffeine⁶.

Caffeine is a Central Nervous System (CNS) stimulant and may cause sleeplessness in susceptible people if it is taken up to several hours before going to bed (doses of 50-200 mg can increase alertness and can decrease fatigue and drowsiness). Therefore, a label warning such as the following should also be included:

- *Caffeine may cause sleeplessness if it is taken up to several hours before going to bed.*

Inclusion of caffeine as an ingredient in multi-component products should be justified with clinical efficacy and safety data (as outlined in *ARGOM Appendix 1 Guidelines on efficacy and safety aspects of OTC applications: Section 9 Fixed combination products*⁷).

Weight control preparations containing caffeine will not be approved.

Camphor

The directions for use for dermal preparations containing camphor should indicate that the product is not to be applied to infants under 12 months of age unless on the advice of a doctor or pharmacist.

Registration of steam inhalant solutions containing camphor will not be approved unless appropriate supporting clinical efficacy and safety data are provided.

See also '[Chest rubs](#)' and '[Easy breathing, use of term](#)'

Cetrimide

Adverse reactions have been reported following repeated application of creams containing more than 1% cetrimide. Topical products containing more than 1% cetrimide will not be approved for registration unless appropriate supporting clinical efficacy and safety data are provided.

⁶ <http://www.foodstandards.gov.au/consumerinformation/caffeine/>

⁷ <http://www.tga.gov.au/industry/otc-argom-app1.htm>

Chest rubs

The use of chest rubs will not be accepted for the treatment of bronchial conditions. The only indications that will be accepted for chest rubs containing ingredients such as eucalyptus oil, menthol, camphor and other aromatics are:

- *May relieve the nasal congestion of colds and make breathing easier (or similar wording).*

The directions for use of chest rubs should include the following statement:

- *Do not apply to infants under 12 months of age unless on the advice of a doctor or pharmacist.*
- *Rub on the chest and/or the throat.*
- *Do not use on the face or anywhere near or in the eyes or nostrils.*

See also '[Camphor](#)', '[Eucalyptus oil](#)' and '[Easy breathing, use of term](#)'

Chlorhexidine

Adverse allergic reactions have been reported for products containing chlorhexidine for use on oral mucosal surfaces. Therefore the labels of products containing chlorhexidine when included in preparations for human use, including preparations for topical use on mucosal surfaces should include warning statements consistent with the following:

- **Avoid contact with eyes.*
- **If in eyes, rinse well with water.*
- **Warning – This product contains chlorhexidine. Severe allergic reactions can occur. Stop use if this occurs.*

For topical products containing chlorhexidine for human use but does NOT include use on mucosal surfaces, statements should be consistent with the following:

- **Avoid contact with eyes.*
- **If in eyes, rinse well with water.*
- **Mild irritation may occur; stop use if it becomes severe.*

Where products containing chlorhexidine for application to mucous membranes have a Product Information (PI) document, the PI should advise of the potential for hypersensitivity reactions to chlorhexidine in both the 'Adverse effects' and 'Contraindications' sections.

Coal tar preparations

All coal tar preparations contain mutagens and are potentially carcinogenic. Justification for the inclusion of coal tar in terms of benefit versus risk should be provided. Indications for use in minor conditions (e.g. napkin rash) will not be accepted.

Because of the potential for increased absorption associated with the use of coal tar under occlusive dressings, the labels (and the CMI and PI, and any package insert, where these are provided) of all topical products containing coal tar should include a warning such as:

- *Not to be used under occlusion except on medical advice.*

The use of a light bandage to prevent staining of clothes is acceptable.

This advice need not be included on the labelling of shampoos or other products which are designed to be washed off after application.

The safety of coal tar on children under 2 years of age has not been established. In addition, although no human data are available on the effects of using coal tar during pregnancy or lactation, the presence of mutagens in the urine has been reported following topical application of coal tar⁸. The labels (and the CMI and PI, and any package insert, where these are provided) of all topical products containing coal tar should therefore include warnings such as:

- *Not recommended for use on children under 2 years of age except under the direction and supervision of a doctor.*
- *Not recommended for use during pregnancy or while breastfeeding.*

As coal tar may cause hypersensitivity reactions and irritation, labels of products containing coal tar should also include warnings such as the following:

- **If irritation occurs, discontinue use.*
- **Avoid contact with the eyes.*
- **Do not use for prolonged periods except on the advice of a doctor.*

In addition, unless otherwise justified, products that are intended for use in psoriasis should include a warning such as:

- *Do not use this product with other forms of psoriasis therapy such as UV radiation or prescription drugs unless directed to do so by a doctor.*

Codeine

Where provided, the Product Information for codeine-containing products should include:

- Under 'Pharmacokinetics' ('Metabolism'): A statement advising that about 8% of patients metabolise drugs poorly via Cytochrome P450 2D6 (CYP2D6), and are likely to obtain reduced pain relief from codeine due to reduced formation of the active metabolite, morphine; and
 - Note:** the 'Pharmacokinetics' section of the Product Information should specifically state that codeine's active metabolite is morphine.
- Under 'Precautions' – 'Interactions with other medicines': A statement advising of the possibility of interactions between codeine and drugs that can inhibit CYP2D6, such as quinidine, phenothiazines and antipsychotic agents.

⁸ Wheeler LA, Saperstein MS & Lowe NJ. Mutagenicity of urine from psoriatic patients undergoing treatment with coal tar and ultraviolet light. *J Invest Dermatol* 77:181-185; 1981.

The CMI for codeine-containing products should advise that about 8% of people are poor metabolisers of codeine, and that poor metabolisers are likely to obtain less pain relief with codeine compared with other people who are not poor metabolisers.

Corn treatments

For products which are indicated for the treatment of corn, statements such as the following should be included on labels:

- *Do not use if you have diabetes or impaired circulation.*
- *Do not use on infants or very young children unless on medical advice.*

Corticosteroid nasal sprays

Some low dose aqueous corticosteroid nasal sprays are scheduled as OTC medicines. Restrictions on dose, pack size and indications (including duration of use and age group) are included in the relevant Schedule entry in the *Standard Uniform Scheduling of Medicines and Poisons* (SUSMP)⁹.

The safety and efficacy data required to support the registration of OTC corticosteroid nasal sprays are as indicated in the *ARGPM Appendix 19 Metered dose aerosols (pressurised and non-pressurised)*¹⁰.

Information consistent with the following should be included either on the product label or in a package insert (e.g. in the CMI, if it is provided as a package insert):

- *Do not exceed the maximum stated dose.*
- *A lower maintenance dose should be used once full effect is obtained.*
- *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:*
 - *you have a nasal or sinus infection*
 - *you have recently had an injury or surgery to your nose*
 - *you have ulceration in your nose*
- *See your doctor or pharmacist if:*
 - *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.*

⁹ <http://tga.gov.au/industry/scheduling-poisons-standard.htm>

¹⁰ <http://www.tga.gov.au/industry/pm-argpm.htm>

Where this information is included in the CMI or other package insert, the label should include a statement such as:

- *Read the enclosed CMI leaflet before starting to use this product (or Read the enclosed leaflet before starting to use this product).*

Decongestant products, nasal

Rebound nasal congestion can occur as a result of continued use of topically administered decongestant nasal products. Such products should contain a statement advising against prolonged use such as:

- *If congestion persists for more than a few days, seek medical or pharmacist advice.*

Decongestant products, oral

Sympathomimetic amines

Because of the unpredictable effect that sympathomimetic amines (e.g. pseudoephedrine and phenylephrine) may have on blood pressure and the risk of interactions with antidepressant medication, product labels should include a warning statement such as:

- **See your doctor before taking this product if you have high blood pressure or heart problems or are taking antidepressant medication.*

Pseudoephedrine is a central nervous system stimulant and may cause sleeplessness if it is taken up to several hours before going to bed in susceptible people. Therefore, the labels of all products that contain pseudoephedrine (including products that also contain a sedating antihistamine or any other ingredient that may have a sedative effect in some people) should include a warning such as:

- **This product/ [product name] may cause sleeplessness if it is taken up to several hours before going to bed.*

Diarrhoea treatments

Labels for all products should include a statement such as:

- *If diarrhoea persists, seek medical advice.*

In infants aged 6 months and under, diarrhoea which persists for longer than six hours requires medical attention, because of the life-threatening consequences of dehydration.

For children aged between 6 months and 3 years, diarrhoea which persists for longer than twelve hours requires medical attention. Although medical consultation is preferable to home treatments, oral rehydration products (electrolyte replacement products) can serve a useful role in reducing the consequences of diarrhoea in this age group.

Children aged 3 years and over should be treated for diarrhoea for only short periods before medical advice is sought.

The directions for use on the labels of products for use as diarrhoea treatments should include the following information:

- For children under 6 months of age: *Medical advice should be sought if diarrhoea persists for more than 6 hours;*
- For children aged 6 months to under 3 years: *Medical advice should be sought if diarrhoea persists for more than 12 hours;*
- For children aged 3-6 years: *Medical advice should be sought if diarrhoea persists for more than 24 hours;*
- For children aged over 6 years: *Medical advice should be sought if diarrhoea persists for more than 48 hours.*

The label or CMI should include a description of the symptoms of dehydration for the benefit of consumers.

Where inorganic adsorbing agents (such as kaolin) are included in a formulation, evidence should be included to show that any other active ingredient is not irreversibly adsorbed or inactivated by the agent. In the absence of supporting clinical data, simple adsorbent preparations for the treatment of diarrhoea will not be registered.

It is considered that there is insufficient evidence to support the use of solanaceous alkaloids in the treatment of diarrhoea in adults or children.

See also [‘Electrolyte replacement products’](#)

Ear drops

Current medical opinion indicates that the use of ear drops should be limited to:

- the prevention or treatment of medically diagnosed otitis externa; or
- the treatment of ‘swimmer’s ear’; or
- wax softening (wax softeners should be bland and non-irritating).

Any other proposed indications should be justified.

Product labels should advise that, in cases of ear perforation (or where there is a likelihood of ear perforation) or where grommets (ventilation tubes) are present, medical advice should be sought before ear drops are used.

Applications for registration of an ear drop containing a local anaesthetic should be accompanied by evidence of safety and efficacy.

‘Easy breathing’, use of term

Terms that imply ‘easy breathing’ may mislead people with asthma. Such terms will not be accepted in isolation, but must be qualified by reference to the actual condition being treated (e.g. “*by drying the secretions of the nose, this product makes breathing easier*”).

Electrolyte replacement products

Electrolyte replacement products should be labelled and formulated to conform to the recommendations of an accepted authority (e.g. the British Pharmacopoeia, World Health Organisation). Other formulations will be considered but must be justified.

See also '[Diarrhoea treatments](#)'

Eucalyptus oil

Eucalyptus oil should not be used in oral preparations (other than as a flavouring agent) because of its toxicity and lack of therapeutic benefit.

In the absence of clinical evidence to support the inclusion of eucalyptus oil in steam inhalant solutions, registration of such products will not be approved.

See also '[Camphor](#)' and '[Easy breathing, use of term](#)'

Expectorants

Guaiphenesin is the only substance recognised as an expectorant. Sponsors wishing to use the term 'expectorant' for any other ingredient should provide clinical data to support the claim.

Eye preparations

The *Therapeutic Goods Order No. 69 - General requirements for labels for medicines*¹¹ requires a statement on the label that eye preparations must be discarded four weeks after the date of initial opening. Consumers will be assisted if space is provided on the label for the user to write the date when the container is first opened.

Applications to register a new eye preparation should address the possibility of interactions between the eye preparation and contact lens materials, and a suitable statement should be included on the product label where appropriate.

Vasoconstrictor eye drops

Warnings to the following effect should be included on the primary pack label or package insert for vasoconstrictor eye drops:

- **Prolonged use may be harmful.*
- **Consult a doctor or pharmacist if using other eye products.*

¹¹ <http://www.comlaw.gov.au/Details/F2009C00264>

- **Do not use if you have glaucoma or other serious eye conditions.*
- **If symptoms persist, consult a doctor.*

The indications for vasoconstrictor eye drops should not include references to close work, tiredness, driving or similar non-specific claims.

The product name and label text should not encourage inappropriate use for trivial or cosmetic purposes. References to 'soothing' or 'whitening' in the presentation of the product will not be accepted.

Fluoride supplements

Fluoride supplements (drops, tablets) should not be taken during pregnancy.

The labelling of fluoride supplement products should include advice consistent with the following:

- **This product should only be used on the advice of a dentist.*
- **Do not use if pregnant.*

Haemorrhoid treatments

For products which are indicated for the treatment of haemorrhoid, the following statements (or similar) should be included on the labels:

- *If symptoms persist, seek medical advice.*

Head lice treatments

Evidence suggests that the efficacy of head lice treatment products is formulation dependent. Sponsors of new products should provide data to support the efficacy of their specific formulation when used according to the directions for use on the product's label.

The efficacy and safety of head lice products should generally be supported by relevant clinical trials, rather than in vitro data only. In vitro data may be acceptable, at the discretion of the TGA, where the formulation of a product is similar to a product registered in Australia that has been fully evaluated, and the sponsor provides a justification in support of the registration of the proposed formulation.

Efficacy data should ideally consist of clinical trials conducted in Australia, to address location-specific resistance issues. Claims for registered products must be limited to control/treatment of head lice and their eggs (except see below regarding prophylactic use). Since no pediculocides have been shown to be 100% insecticidal and ovicidal under all conditions of use, claims must not state or imply that one treatment can kill all lice and their eggs.

Sponsors must not claim prophylactic use (preventative or repellent action) as an indication unless they can provide satisfactory evidence that such use of the product will

not promote the development of resistance. Safety and efficacy of prophylactic use must also be supported by clinical trial data.

The use of lindane and benzyl benzoate in products registered for the treatment of head lice infestation is discouraged.

Labels and/or package inserts should include information consistent with the following (or information consistent with the clinical trial protocol as appropriate) immediately after the dosage instructions:

1. *Use enough to thoroughly cover the scalp, including the back of the neck and behind the ears.*
2. *If the product gets into the eyes, rinse out immediately with water.*
3. *Remove all the eggs (nits) you can find after treatment (this is easier with a fine tooth comb and hair conditioner on wet or dry hair).*
4. *Repeat the treatment after 7-10 days to kill lice that have hatched from any remaining eggs that were not killed by the first treatment.*
5. *If you find live lice or more eggs appear after the second treatment, seek advice from a health care professional.*
6. *Only use the product when you can see live lice or their eggs. Don't use regularly or to prevent head lice.*
7. *Check other people in the household and treat if necessary. Lice can quickly spread back to people who have already been treated.*
8. *Don't use on babies under 6 months, except on medical advice.*

Because education is an important component of treatment, sponsors are encouraged to make available relevant public health information on the treatment of head lice infestation in a package insert, a web site referenced on the label or by other means (e.g. a telephone information service).

Further information on head lice products is included in the document, *A review of the regulation of head lice preparations in Australia*, which is available on the TGA website¹².

See also '[Lindane](#)'

Hydroquinone

Use of hydroquinone to treat the hyperpigmentation caused by pregnancy will not be approved, as this condition is self-limiting.

In addition to the label warnings required by the RASML, labels of products containing hydroquinone should include the following warning:

- **Long term and repeated use should be avoided because darkening of the skin could occur.*

Other substances in the formulation may enhance absorption of hydroquinone. Sponsors should take this into account in formulating products and address this issue as part of the registration application.

¹² <http://www.tga.gov.au/archive/review-headlice-preparations-040715.htm>

Hypoallergenicity of topical preparations

Where a product contains a claim of hypoallergenicity, evidence must be provided that the product has been tested in hypersensitive subjects or found to pass a suitable test such as the Kligman Maximisation Test. The guinea pig (Kligman) maximisation test, Buehler test and mouse local lymph node assay are internationally accepted, routine assays for testing sensitisation potentials of chemicals/drugs. However, of these tests, only the Guinea pig maximisation test uses a test method of "maximising"/"magnifying" the sensitising effects of the test material since this test involves intra-dermal injection and adjuvant to "magnifying" the sensitising activity of the test material.

Repeat Insult Patch Testing (RIPT) is not a suitable substitute, as it is not conducted in a system that has magnified responsiveness as would be encountered in a sensitive individual.

Ibuprofen

Indications

Sponsors may use indications consistent with any or all of the representative indications set out below, as appropriate to a particular product, without the need to supply supporting efficacy data:

- For the temporary relief of pain (and discomfort) and/or inflammation associated with:
 - headache
 - migraine headache
 - tension headache
 - sinus pain
 - toothache
 - dental procedures
 - backache
 - muscular aches and pains
 - arthritis
 - osteoarthritis
 - rheumatic pain
 - menstruation/period pain
 - fibrositis
 - neuralgia
 - sore throat
 - tennis elbow
 - colds and flu
- Reduces fever and/or the discomfort associated with fever.

For paediatric formulations, relief of pain and discomfort associated with teething, earache and immunisation may be added to any of the above, as appropriate to the age group.

Sponsors may propose other indications but should contact the OTC Medicines Evaluation for advice on whether data will be required to support the safety and efficacy of the product for those indications.

Combination OTC analgesic products that contain ibuprofen and codeine may include claims of 'strong' or 'powerful' pain relief (or similar). These claims will not be accepted for products that contain ibuprofen as the only analgesic agent, or ibuprofen in combination with another analgesic agent, unless the claims are justified on the basis of clinical efficacy data.

As fever is a normal and generally beneficial response to infection, no elaboration to the words "*reduces fever*" will be accepted except in the context of duration of treatment, relief of discomfort associated with fever or examples of conditions where fever may occur.

Dose

Adult dosage

Adult dosage recommendations (adults and children 12 years and over):

- 200 mg to 400 mg every four to six hours as necessary. Dosage should not exceed 1200 mg (expressed on the label as the number of units, for example tablets) in 24 hours.

Paediatric dosage

Paediatric dosage recommendations (3 months to 12 years):

- The recommended paediatric dose is 5-10 mg/kg/dose. Doses should be given every 6-8 hours as necessary with no more than four doses in 24 hours.

Where dosage instructions for children under 12 months of age are included on the labelling, the dosage instructions (see Table 1) must include statements advising that the product should not be given to infants under 3 months, and that it should only be given to infants aged 3-12 months following the advice of a doctor.

Labels could include appropriate discrete doses (consistent with the table below), instead of dosage ranges. E.g. for children aged 1-3 years, the label could include a dose equivalent to 100 mg (rather than a dosage range, such as 80-120 mg).

Wider age ranges (e.g. 1-3 years) could be used on product labelling where appropriate.

Table 1. Ibuprofen dosage for children aged 3 months to 12 years.

Age	Average body weight (kg)	Dose (mg)
3 – 6 months	6 – 8 kg	40 – 60 mg
6 – 12 months	8 – 10 kg	60 – 80 mg
1 – 2 years	10 – 12 kg	80 – 100 mg
2 – 3 years	12 – 14 kg	100 – 120 mg
3 – 4 years	14 – 16 kg	120 – 140 mg
4 – 5 years	16 – 18 kg	140 mg

Age	Average body weight (kg)	Dose (mg)
5 – 6 years	18 – 20 kg	140 – 160 mg
6 – 7 years	20 – 22 kg	160 – 180 mg
7 – 8 years	22 – 25 kg	180 – 200 mg
8 – 9 years	25 – 28 kg	200 – 220 mg
9 – 10 years	28 – 32 kg	220 – 240 mg
10 – 11 years	32 – 36 kg	240 – 280 mg
11 – 12 years	36 – 41 kg	280 – 300 mg

Paediatric dosage – Liquid dose products

Where possible, dose volumes of liquid products should be expressed in whole numbers of mL. Doses should be presented with age, weight and volumes unless otherwise justified.

Recommended doses should be able to be measured using commonly available metric measuring devices or an appropriate measuring device provided with the product. There may be instances where doses need to be slightly different from the recommended milligram doses given above, depending on the ibuprofen concentration of the product, and/or the calibrations on dosing devices.

Sponsors intending to supply measuring devices with the product should refer to *ARGOM Appendix 2 – Guidelines on quality aspects of OTC application: Section 8 Finished product container*¹³. Calibrations on measuring devices should be exclusively in metric units and should allow all the doses shown on the labels to be measured accurately. A sample of the proposed measuring device, or information on the calibrations intended for the measuring device, should be provided with the submission.

Dosage instructions could include advice consistent with the following:

- *If you know that your child's weight is less than the weight corresponding to their age in the table, choose the dose for their weight.*

Paediatric dosage – Solid dose products

Solid dose products that are intended to be swallowed whole should not include directions for use by children aged six years and under. Recognising that dosing with solid dose products is less flexible than with liquid products, these products could include a dose of 200 mg every 6-8 hours as necessary, with no more than four doses in 24 hours, for children aged 7-12 years.

Solid dosage forms that are specially designed and suitable for administration to younger children (e.g. chewable tablets) may be indicated for use in children from two years of age.

¹³ <http://www.tga.gov.au/industry/otc-argom-app2.htm>

Differentiation of strengths

Sponsors should give close consideration to the labelling and presentation of different strength liquid and solid dose ibuprofen products, with the aim of minimising the possibility that the wrong dose may accidentally administered or taken.

Combination products

Products containing ibuprofen together with one or more other active ingredients which are similar to existing registered products will usually not require efficacy or safety data, provided they comply with the guideline on fixed dose combination products (see *ARGOM Appendix 1 – Guidelines on efficacy and safety aspects of OTC application: Section 9 Fixed dose combination products*¹⁴). Where new combinations are proposed (i.e. combinations and/or strengths that are not included in the ARTG for supply in Australia), the safety and efficacy of the combination will need to be justified.

See also '[Paediatric products](#)'

Iodine

See '[Povidone-iodine/iodine – dermal](#)'

Kaolin

See '[Diarrhoea treatments](#)'

Laxatives

This guideline applies to any OTC laxative product, including oral dose forms, enemas and suppositories.

The correct management of uncomplicated constipation consists of correct diet, adequate fluid intake and suitable exercise. In cases where occasional treatment is required, the use of bulking agents is viewed favourably.

Product labels should include the following advice:

- *Drink plenty of water;*
- *Increase fibre in diet except in cases of medication-induced constipation (e.g. with codeine);*
- *Prolonged use of laxatives is undesirable and may lead to dependence (this advice does not apply to bulk forming agents); and*

¹⁴ <http://www.tga.gov.au/industry/otc-argom-app1.htm>

- *If symptoms persist seek medical advice.*

Weight reduction claims will not be approved for products containing laxative ingredients.

Use of the term 'gentle' will not be approved in relation to products containing a stimulant laxative (e.g. senna alkaloids, bisacodyl).

The labels of products containing senna alkaloids, aloe or cascara should include a statement such as:

- **Do not use when abdominal pain, nausea or vomiting is present. If you are pregnant or breast feeding, seek medical advice before taking this product.*

Products containing purgative ingredients, such as jalap, podophyllum or wahoo, are not regarded as acceptable therapy for the treatment of simple constipation.

Lignocaine

See '[Anaesthetics, dermal](#)'

Lindane

Questions have been raised concerning the safety of the use of lindane for the treatment of head lice, body lice, crab lice, and scabies infestations. Serious adverse reactions to products containing lindane may result from incorrect use of the products. However, evidence from the literature shows that lindane has been used safely and effectively in millions of patients.

While it is unlikely that applications will be made for the registration of new products containing lindane, it is important to maintain access to these products for use in treatment of Norwegian scabies or in case of resistance to other agents.

The labels of products containing lindane must include warning statements consistent with the following:

- **This preparation must not be used on broken skin.*
- **This preparation should be used with caution on infants, small children and pregnant or lactating women. Medical advice should be sought before use.*

See also '[Head lice treatments](#)'

Lozenges

See '[Anaesthetic lozenges](#)' and '[Sore throat treatments – antimicrobial](#)'

Mebendazole

See '[Anthelmintics](#)'

Metered dose inhalers

Spacer devices

A statement consistent with the following should be included in the Product Information of metered dose inhaler products used in the treatment of respiratory disorders such as asthma and chronic obstructive airways disease:

- *Children and many other people will benefit from the consistent use of a spacer device with their metered dose inhaler (MDI or 'puffer'), particularly those with poor inhaler technique. Use of a spacer will also decrease the amount of medicine deposited in the mouth and back of the throat, and therefore reduce the incidence of local side effects such as mouth and throat irritation.*
- *In those people using a spacer, a change in formulation of the medicine used, or a change in the make of spacer may be associated with alterations in the amount of medicine delivered to the lungs. The clinical significance of these alterations is uncertain. However, in these situations, the person should be monitored for any loss of asthma control.*
- *If using a spacer, the patient should be instructed to breathe in and out several times after each release into the spacer. Any delay should be kept to a minimum.*
- *Because of electrostatic charge, leading to adherence of medicine particles to the walls of the spacer, spacers should be washed in warm water with kitchen detergent and left to drain dry (without rinsing) before initial use and at least monthly thereafter. A cloth should not be used to dry the spacer, as this can produce more static electricity.*

The Product Information should include information on compatible spacers, and should recommend that patients are directed to read the instructions that come with the spacer.

Consistent advice should also be included on the label and/or in the CMI (or other package insert).

Mouth ulcers, relief

Product labels should include a statement such as:

- *If symptoms persist, seek medical or dental advice.*

The efficacy of any antiseptic active ingredient in products indicated for the relief of mouth ulcers must be justified.

See also [‘Teething products’](#)

Mouthwashes, antiseptic

Claims of antiseptic activity must be accompanied by evidence of efficacy. Any claims relating to the duration of action will require justification.

Nappy rash

Local anaesthetics and boric acid are not acceptable in any form for the treatment of nappy rash.

Nicotine replacement therapy

Data requirements

Nicotine Replacement Therapy (NRT) products are modified release products, and are considered to be formulation and delivery system dependent. Applications to register new NRT products should generally include a full data package, unless otherwise justified.

A full data package comprises:

- Preclinical (toxicology) data
- Formulation-specific pharmacokinetic data
- Local tolerance data
- Clinical efficacy and safety studies (to justify the intended dosage of the product, including the dose size, frequency and duration of use).

Full data package

The following are examples of cases where a full data package will be required:

New NRT dose forms

NRT dose forms that are not currently registered in Australia will require a full data package. Formulation-specific clinical data should be provided to justify the efficacy and safety of the proposed product, and the intended dosage size, frequency and duration of use of the product.

New nicotine molecule

NRT products that contain forms of nicotine (e.g. salts, complexes) that are not currently registered in Australia will require a full data package to justify the efficacy and safety of the proposed products.

Products containing the following forms of nicotine have been approved by the TGA:

- Anhydrous nicotine
- Nicotine polacrilex
- Nicotine betadex complex
- Nicotine bitartrate dihydrate.

The ARTG should be checked for the most current information.

Sponsors who propose to provide an application for registration of a new NRT product without clinical efficacy and safety data should discuss the application with the TGA prior to submission.

Justification for not submitting clinical efficacy data

A justification for not submitting clinical efficacy and safety data may be acceptable in some situations, including the following:

New form of nicotine, registered dosage form

In the case of a product containing a new form of nicotine and a dosage form that has been approved in Australia, clinical efficacy data may not be required. However, the following data will be required:

- Preclinical toxicology data;
- Formulation-specific pharmacokinetic data; and
- Local tolerance data.

Bioequivalence or bioavailability data may also be required (see *ARGOM Appendix 1 - Guidelines on efficacy and safety aspects of OTC applications*¹⁵).

Modified release oral (buccal/sublingual) products, other than chewing gums

Single dose and multiple dose pharmacokinetic studies should be provided to support the registration of modified release oral NRT dosage forms intended for buccal/sublingual absorption.

Where the dosage form of a new modified release oral (buccal/sublingual) NRT product differs from the dosage forms currently approved for use in Australia, clinical efficacy and safety data should be provided, unless otherwise justified.

In place of clinical efficacy and safety data, submission of bioequivalence or other bioavailability/pharmacokinetic data comparing the proposed product and a relevant currently registered Australian product may be acceptable, if the sponsor can justify that the proposed and comparator products have the same methods of administration / absorption. The sponsor must justify any differences in the directions for use between the proposed and comparator products, if clinical efficacy and safety data are not provided.

See *ARGOM Appendix 1 - Guidelines on efficacy and safety aspects of OTC applications*¹⁶ for information on bioequivalence/bioavailability data requirements.

Local tolerance data using the proposed formulation should also be provided, unless otherwise justified.

Higher strength NRT products

For applications to register new NRT products with the same dosage form, but higher strengths than those currently approved for use in Australia, sponsors should provide the following data:

- Preclinical safety data, unless otherwise justified;
- Local tolerance data using the proposed formulation (to demonstrate that the higher nicotine strength does not adversely affect local tolerance), unless otherwise justified; and
- Clinical safety data using the proposed higher strength product formulation.

¹⁵ <http://www.tga.gov.au/industry/otc-argom-app1.htm>

¹⁶ <http://www.tga.gov.au/industry/otc-argom-app1.htm>

Lower strength NRT products

For applications to register new NRT products with the same dosage form, but lower strengths than those currently approved for use in Australia, sponsors should provide the following data:

- Bioavailability data and/or clinical efficacy data comparing the proposed formulation with a formulation currently registered in Australia; and
- Local tolerance data using the proposed formulation, unless otherwise justified.

Bioequivalence/Pharmacokinetic data

Bioequivalence or pharmacokinetic data, but not clinical efficacy/safety data, may be acceptable as support for some applications, including the following:

Reformulation of an existing product, or addition of a new flavour of a currently registered product

Data showing bioequivalence of the new product with a relevant formulation/flavour currently registered by the sponsor in Australia should be provided. The TGA may consider a justification for not providing bioequivalence data, only if the proposed changes to the formulation are minor.

Local tolerance data using the proposed formulation should also be provided (to demonstrate that the changes to the flavour and/or other formulation details do not adversely affect local tolerance), unless otherwise justified.

Generic products

Where a new product contains the same dosage form, same strength and same form of nicotine as a currently registered Australian NRT product (e.g. a generic 2 mg or 4 mg nicotine chewing gum containing nicotine polacrilex), data showing bioequivalence of the proposed and comparator products should be provided. Clinical efficacy data will not be required.

Where registration of two or more different strengths of a generic dosage form is proposed, the sponsor should submit bioequivalence data for each strength, or a justification for not providing these data.

Local tolerance data using the proposed formulation should also be provided (to demonstrate that any formulation differences do not adversely affect local tolerance), unless otherwise justified.

Indications

Single NRT product types have been approved for use in Australia for the following standard indications:

- Use as an aid in the cessation of smoking in smokers with nicotine dependence; and
- Relief of nicotine withdrawal symptoms, including nicotine cravings, associated with smoking cessation.

Other indications approved for specific NRT products

In addition to use of single NRT product types for the standard indications above, the TGA may consider other indications that have been approved in Australia for specific NRT dosage forms or NRT combinations, without requiring additional formulation-specific clinical data or a literature-based submission¹⁷. Applications for the following indications will currently be considered:

1. Combination therapy using nicotine transdermal patches and intermittent use products:
 - Nicotine transdermal patches plus 2 mg nicotine gums, where both components are currently registered in Australia or are shown to be bioequivalent to relevant originator products currently registered in Australia.
 - Nicotine transdermal patches plus 1.5 mg or 2 mg nicotine lozenges, where both components are currently registered in Australia or are shown to be bioequivalent to relevant originator products currently registered in Australia.
2. Smoking reduction prior to stopping smoking – use of intermittent dosing nicotine products by smokers who are unable or not ready to stop smoking abruptly, as a step towards stopping completely:
 - Nicotine chewing gums that are currently registered in Australia, or are shown to be bioequivalent to nicotine 2 mg or 4 mg chewing gum products currently registered in Australia.
 - Nicotine inhalers that are bioequivalent to the originator inhalers providing nicotine for buccal absorption registered in Australia.
 - Nicotine lozenges that are bioequivalent to the originator lozenges registered in Australia.
3. Pre-cessation use of nicotine transdermal patches (use by smokers for two weeks, prior to quitting smoking):
 - Nicotine transdermal patches that are considered to be bioequivalent to the relevant originator transdermal patches currently registered in Australia.

Applications for approval of combination NRT or use of NRT for smoking reduction should include formulation-specific clinical efficacy and safety data, or a justification for not providing these data (which could include a literature-based submission), to justify:

- Directions for use that differ from those approved for currently registered Australian products; or
- Use with other NRT products, or different strengths of the NRT products listed above.

New indications

Sponsors wishing to include new indications and/or directions for use of currently registered NRT products should provide clinical efficacy and safety data, or a literature-based submission, to justify the requested amendments (see *ARGOM Appendix 1- Guidelines on efficacy and safety aspects of OTC applications*¹⁸).

¹⁷ <http://www.tga.gov.au/industry/pm-literature-based-submissions.htm>

¹⁸ <http://www.tga.gov.au/industry/otc-argom-app1.htm>

Labelling and other product documentation

Primary pack labels of unscheduled NRT products should include the statement “*Keep out of reach of children*” prominently on the main panel of the label as a stand-alone statement (on a line by itself). It is preferable for this statement to be located above the product name.

A Product Information (PI) document is required for all NRT products, regardless of poisons scheduling. A package insert, which could be in the form of CMI, should be provided for all NRT products, unless all relevant information (including all the contraindications, precautions and detailed instructions for use) are included on the label of the primary pack.

Some NRT transdermal patch products contain traces of aluminium or other metals to help them stick to the skin. Patches may contain enough of the metal to conduct electricity, overheat and cause a burn similar to bad sunburn, if the patches are worn during procedures such as Magnetic Resonance Imaging (MRI) scans. The PI and CMI (or other package insert) for nicotine transdermal patches that may contain traces of aluminium or other metals should include warnings that the patch should be removed prior to undergoing any MRI procedures.

Nonoxinol 9

In vivo scientific evidence will be required to support any application for registration of products containing nonoxinol 9 as anti-viral agents.

Nonoxinol 9 is considered to have spermicidal activity provided it is in an appropriate delivery system.

Package inserts (or carton labels if there is no package insert) of products containing nonoxinol 9 for use as a spermicidal contraceptive should include warnings consistent with the following:

- *For vaginal use only.*
- *This product should not be used rectally.*
- **Sexually transmitted diseases (STDs) alert:** *This product does **not** protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs).*
- *Ask a doctor before use if you have a new sex partner, multiple sex partners, or unprotected sex. Frequent use (more than once a day) of this product may increase vaginal irritation, which may increase the risk of becoming infected with the AIDS virus (HIV) or other STDs from infected partners. Ask a doctor or other health professional for your best birth control method.*
- *Stop use and ask a doctor if you or your partner get burning, itching, a rash, or other irritation of the vagina or penis.*

Paediatric products

This guideline applies to medicines that are indicated for use in children (including products that are intended for use in both adults and children). Where label statements are specified, the wording may be varied provided the intent remains the same.

Where the TGA has not previously approved a substance for use in children, or in children in a specific age group, sponsors will be required to submit clinical data to justify the efficacy and safety of that substance in the requested age group. In some cases, a justification based on specific pharmacokinetic data and safety data relevant to the requested age group may be acceptable.

Where product labels only include doses for adults and/or children over a particular age (e.g. adults and children 12 years and over; adults and children 6 years and over; children 6-12 years), the labels should include a statement such as *“Do not give to children under xx years/months”*.

Where the labels do not include doses for children under a particular age, inclusion of a label statement such as *“Do not give to children under xx years except on medical advice”* or *“Not recommended for use in children under xx years/months except on the advice of a doctor (or pharmacist)”* is only acceptable if the product has an approved published Product Information that the doctor (or pharmacist) can refer to in determining the appropriate dose for this age group.

Use in children under 6 months of age

Medicines generally should not be administered to children under 6 months of age except on the advice of a doctor because:

- serious illnesses in this age group often produce subtle or non-specific symptoms. Sedative, antipyretic and other drugs may confuse the clinical picture, delaying correct diagnosis and treatment; and
- correct dosage calculation based on weight is essential for many medicines for use in this age group.

Unless otherwise justified, where dosage instructions for children under 6 months of age are included on the labelling, the dosage instructions should advise (at the beginning of the directions for use in this age group) that the product is only to be given in this age group following the advice of a doctor.

In the case of products which are not absorbed systemically and are used for self-limiting conditions (e.g. simethicone ‘wind’ drops), inclusion of a statement such as the following may be considered:

- *Seek the advice of a doctor or pharmacist before using for the first time in children under 6 months of age.*

Paediatric cough, cold and flu products

A review¹⁹ by the TGA of OTC cough and cold medicines for children aged 2-12 years has concluded that, in light of the current lack of evidence of efficacy and the historical profile of adverse drug reactions (ADRs) in Australia and overseas, it is likely that the risks associated with the use of cough and cold preparations in children outweigh the benefits for children below the age of 6 years. There is currently a lack of evidence of efficacy for cough and cold medicines in children aged 6 to 12 years of age. Additionally, the historical profile of adverse drug reactions indicates that there are potential risks involved in use of these medicines in that age group.

Following this review, the TGA has agreed that OTC cough and cold products containing any of the following ingredients should not be used for the treatment of children under 6 years of age, and should only be administered to children aged 6-11 years on the advice of a doctor, pharmacist or nurse practitioner

- bromhexine
- dihydrocodeine
- phenylephrine
- brompheniramine
- diphenhydramine
- pholcodine
- carbetapentane
- doxylamine
- promethazine
- chlorpheniramine
- guaiphenesin
- pseudoephedrine
- codeine
- ipecacuanha
- senega and ammonia
- dexchlorpheniramine
- oxymetazoline
- triprolidine
- dextromethorphan
- peniramine
- xylometazoline

The following table provides guidance for statements required for labels of cough, cold and flu products.

Table 2. Statements required for labels of cough, cold and fly products.

Labels of products	Statements
Which include dosage instructions for children aged from 6 years	<p><i>Do not give to children under 6 years of age.</i></p> <p>and</p> <p><i>Do not give to children aged between 6 and 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</i></p>

¹⁹ <http://www.tga.gov.au/archive/consult-labelling-cough-cold-091022.htm>

Labels of products	Statements
Which include dosage instructions for children aged from 'x' years, where 'x' is 7, 8, 9, 10 or 11 years	<p><i>Do not give to children under 'x' years of age.</i></p> <p>and</p> <p><i>Do not give to children aged between 'x' and 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</i></p> <p>or</p> <p><i>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</i></p>
Which does not include dosage instructions for children aged under 12 years	<i>Do not give to children under 12 years of age.</i>

Registration of single active ingredient products for relief of specific symptoms of colds and flu in children aged under 2 years may be acceptable. For example, OTC analgesic products containing ibuprofen or paracetamol for relief of pain and discomfort and/or reduction of fever associated with colds and flu may be registered, provided those products comply with the ARGOM guideline on '[Ibuprofen](#)' or '[Paracetamol](#)'.

Paediatric products containing sedating antihistamines (other than cough, cold and flu products)

OTC products containing sedating antihistamines (including chlorpheniramine, brompheniramine, dexchlorpheniramine, diphenhydramine, doxylamine, pheniramine, promethazine, trimeprazine, triprolidine) that are approved for paediatric use for indications other than coughs, colds and flu (e.g. for use in allergic conditions, as an antiemetic and/or sedation) must not include directions for use in children under 2 years of age on the labelling or Product Information. Any product containing a sedating antihistamine and indicated for children under 2 years is only available as a 'Prescription only medicine' (Schedule 4 of the SUSMP²⁰).

The following table provides guidance for statements required for labels of products containing sedating antihistamines that are approved for paediatric use for allergic conditions and/or as an anti-emetic.

²⁰ <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>

Table 3. Statements required for labels of products containing sedating antihistamines approved for paediatric use for allergic conditions and/or as an anti-emetic.

Labels of products	Statements
Which include dosage instructions for children aged from 2 years	<i>Do not give to children under 2 years of age.</i>
Which include dosage instructions for children aged from 'x' years, where 'x' is 3, 4, 5, 6, 7, 8, 9, 10 or 11 years	<i>Do not give to children under 'x' years of age.</i>
Which does not include dosage instructions for children aged under 12 years	<i>Do not give to children under 12 years of age.</i>

The statements contained in the above table must be placed together with the corresponding dosage instructions for allergies and/or anti-emetic use.

Additional requirements for paediatric products containing sedating antihistamines that include indications for sedation

OTC products containing some sedating antihistamines (e.g. diphenhydramine, promethazine, trimeprazine) may be approved for short-term use for sedation. This may be in addition to other indications (e.g. for use in allergic conditions and/or as an anti-emetic).

The labels of OTC products containing sedating antihistamines that are approved for indications that include short-term use for sedation in children must include advice that the products should only be used for sedation in children aged 2-11 years on the advice of a doctor or pharmacist.

The following table provides guidance for statements required for labels of products containing sedating antihistamines that include indications for sedation.

Table 4. Statements required for labels of products containing sedating antihistamines that include indications for sedation.

Labels of products	Statements
Which include dosage instructions for sedation in children aged from 2 years	<i>Do not give to children under 2 years of age.</i> and <i>Do not give to children aged between 2 and 11 years for sedation, except on the advice of a doctor or pharmacist.</i>

Labels of products	Statements
Which include dosage instructions for children aged from 'x' years, where 'x' is 3, 4, 5, 6, 7, 8, 9, 10 or 11 years	<p><i>Do not give to children under 'x' years of age.</i></p> <p>and</p> <p><i>Do not give to children aged between 'x' and 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</i></p> <p>or</p> <p><i>Do not give to children aged 11 years, except on the advice of a doctor, pharmacist or nurse practitioner.</i></p>

The statements contained in the above table must be placed together with the corresponding dosage instructions for sedation.

See also [‘Antihistamines – Use as hypnotics’](#)

Solid dose products for paediatric use

In general, products in solid dosage forms (e.g. tablets, capsules) should not be labelled for use in children aged 6 years and under, because of the danger of inhalation. Where other presentations more suitable for use in this age group are available (e.g. oral liquid products, chewable tablets or dissolve in the mouth formats), the dosage instructions on the label of the solid dosage form could advise of the availability of these other presentations.

Chewable tablets and ‘dissolve in the mouth’ dosage forms may be indicated for use in children aged 2 years and over:

- For chewable tablets, the dosage instructions should clearly state that the tablets are intended to be chewed, and should not be swallowed whole. The directions for use should also advise that the tablets should not be given to children unless the parent or carer is sure the child can chew the tablets.
- For ‘dissolve in the mouth’ dosage forms, the dosage instructions should clearly state that the product is intended to be dissolved in the mouth, and should not be swallowed whole. The directions for use should also advise that the product should not be given to children unless the parent or carer is sure the child is able to dissolve the product in the mouth.

If an alternative presentation is not available, and a solid dose product (that is not a chewable tablet, ‘dissolve in the mouth’ dosage form or other format that is not intended to be swallowed whole) is indicated for use in children, the label should include appropriate dosage instructions for use in children. For example, if appropriate and the formulation permits, the label could advise that the tablets should be crushed or capsules emptied and the contents mixed with water, jam or honey before administering to young children or any individual who has difficulty swallowing tablets or capsules.

See also [‘Anaesthetic lozenges’](#), [‘Chest rubs’](#), [‘Corn treatments’](#), [‘Diarrhoea treatments’](#), [‘Fluoride supplements’](#), [‘Ibuprofen’](#), [‘Paracetamol’](#) and [‘Teething products’](#)

Paracetamol

Indications

Sponsors may use indications consistent with any or all of the representative indications set out below, as appropriate to a particular product, without the need to supply supporting efficacy data:

- For the temporary relief of pain (and discomfort) associated with:
 - headache
 - migraine headache
 - tension headache
 - sinus pain
 - toothache
 - dental procedures
 - backache
 - muscular aches and pains
 - arthritis
 - osteoarthritis
 - rheumatic pain
 - menstruation/period pain
 - fibrositis
 - neuralgia
 - sore throat
 - tennis elbow
 - colds and flu.
- Reduces fever and/or the discomfort associated with fever

For paediatric formulations, relief of pain and discomfort associated with teething, earache and immunisation may be added to any of the above, as appropriate to the age group.

Sponsors may propose other indications but should contact the TGA for advice on whether data will be required to support the safety and efficacy of the product for those indications.

Combination OTC analgesic products that contain paracetamol and codeine may include claims of 'strong' or 'powerful' pain relief (or similar). These claims will not be accepted for products that contain paracetamol as the only analgesic agent, or paracetamol in combination with another analgesic agent, unless the claims are justified on the basis of clinical efficacy data.

As fever is a normal and generally beneficial response to infection, no elaboration to the words "*reduces fever*" will be accepted except in the context of duration of treatment, relief of discomfort associated with fever or examples of conditions where fever may occur.

Dose

Adult dosage

Adult dosage recommendations (adults and children 12 years and over):

- 500 to 1000 mg every four to six hours as necessary. Dosage should not exceed 4 g (expressed on the label as number of units, for example tablets) in 24 hours.

Paediatric dosage

Paediatric dosage recommendations (1 month to 12 years, see also Table 5):

- The dose should be based on 15 mg/kg, with the understanding that dosing with solid dose products in children is less flexible than with liquid products.
- Doses should be given every four to six hours as required with not more than four doses in 24 hours.
- The total **daily** dose should not exceed 60 mg/kg except on medical advice.

The labels should advise that the product should not be administered for more than 48 hours except on medical advice, and (where doses are included for children aged from one month) that administration to children under one month is not recommended.

Labels could include appropriate discrete doses (consistent with the table below), instead of dosage ranges. For example, for children aged 1-3 years, the label could include a dose equivalent to 180 mg (rather than a dosage range, such as 150-210 mg).

Wider age ranges (e.g. 1-3 years) could be used on product labelling where appropriate.

Table 5. Paracetamol dosage for children aged 1 month to 12 years.

Age	Average body weight (kg)	Single dose (mg)
1 – 3 months	4 – 6	60 – 90
3 – 6 months	6 – 8	90 – 120
6 – 12 months	8 – 10	120 – 150
1 – 2 years	10 – 12	150 – 180
2 – 3 years	12 – 14	180 – 210
3 – 4 years	14 – 16	210 – 240
4 – 5 years	16 – 18	240 – 270
5 – 6 years	18 – 20	270 – 300
6 – 7 years	20 – 22	300 – 330
7 – 8 years	22 – 25	330 – 375
8 – 9 years	25 – 28	375 – 420
9 – 10 years	28 – 32	420 – 480

Age	Average body weight (kg)	Single dose (mg)
10 – 11 years	32 – 36	480 – 540
11 – 12 years	36 – 41	540 – 615

Paediatric dosage – Liquid dose products

Where possible, dose volumes of liquid products should be expressed in whole numbers of mL. Doses should be presented with age, weight and volumes unless otherwise justified.

Recommended doses should be able to be measured using commonly available metric measuring devices or an appropriate measuring device provided with the product. There may be instances where doses need to be slightly different from the recommended milligram doses given above, depending on the paracetamol concentration of the product, and/or calibrations on dosing devices.

Sponsors intending to supply measuring devices with the product should refer to *ARGOM Appendix 2 – Guidelines on quality aspects of OTC application: Section 8 Finished product container*²¹. Calibrations on measuring devices should be exclusively in metric units and should allow all the doses shown on the labels to be measured accurately. A sample of the proposed measuring device, or information on the calibrations intended for the measuring device, should be provided with the submission.

Dosage instructions could include advice consistent with the following:

- *If you know that your child's weight is less than the weight corresponding to their age in the table, choose the dose for their weight.*

Paediatric dosage – Solid dose products

Solid dose products that are intended to be swallowed whole should not include directions for use by children aged 6 years and under. Recognising that dosing with solid dose products is less flexible than with liquid products, these products could include a dose of 250 to 500 mg every 4-6 hours as necessary, with no more than four doses in 24 hours, for children aged 7-12 years.

Solid dosage forms that are specially designed and suitable for administration to younger children (e.g. chewable tablets) may be indicated for use in children from two years of age.

Product strength and pack size – liquid preparations

Sponsors may supply any or all of the following strengths of paracetamol liquid without the need for justification: 24 mg/mL, 48 mg/mL, 50 mg/mL and 100 mg/mL. Deviation from these strengths requires justification.

While not prohibited, the introduction of pack sizes larger than 200 mL will require justification.

²¹ <http://www.tga.gov.au/industry/otc-argom-app2.htm>

Differentiation of strengths

Sponsors should give close consideration to the labelling and presentation of different strength liquid and solid dose paracetamol products, with the aim of minimising the possibility that the wrong dose may accidentally administered or taken.

Combination products

Products containing paracetamol together with one or more other active ingredients which are similar to existing registered products will usually not require efficacy or safety data, provided they comply with the guideline on fixed dose combination products (see *ARGOM Appendix 1 – Guidelines on efficacy and safety aspects of OTC application: Section 9 Fixed dose combination products*²²). Where new combinations are proposed (i.e. combinations and/or strengths that are not included in the ARTG for supply in Australia), the safety and efficacy of the combination will need to be justified.

Due to the lack of flexibility when dosing with combination products, and because the majority of patients require more than 500 mg of paracetamol for effective analgesia, products should be formulated so that doses of other ingredients are at safe and effective levels when at least 600 mg of paracetamol is taken.

See also '[Paediatric products](#)'.

Phenylalanine

See '[Aspartame](#)'

Phenylephrine

See '[Decongestant products, oral](#)'

Povidone-iodine/iodine – dermal

Products for dermal use should contain a statement such as:

- **If skin irritation or rash occurs, discontinue use immediately.*

Pseudoephedrine

See '[Decongestant products, oral](#)'

²² <http://www.tga.gov.au/industry/otc-argom-app2.htm>

Rubefacients

The following indications (or similar) will generally be accepted for rubefacient products:

- *For the temporary relief of the pain of rheumatism, arthritis, fibrositis, lumbago, muscular aches and strains.*

Lumbago is defined as backache in the lumbar or lumbosacral regions.

Sciatica, neuritis, bruising, swelling or cramps will not be approved as indications for rubefacient products unless the sponsor provides evidence of the efficacy and safety of the product for the requested indication(s).

Due to the possibility of myolysis when rubefacients are used in conjunction with heat pads, product labels should contain a statement such as:

- *This product should not be used in conjunction with heat pads.*

Sodium bicarbonate

The use of sodium bicarbonate and other alkaline bicarbonates as antacids is undesirable. While effervescent preparations containing sodium bicarbonate will be considered for registration, products containing high levels of sodium and bicarbonate are discouraged.

See also '[Sodium content](#)'.

Sodium content

Products for oral administration containing more than 120 mg of sodium per maximum recommended daily dose should comply with the requirements of *Therapeutic Goods Order No. 69 - General requirements for labels for medicines*²³.

The sodium content of the formulation should be justified for products for oral administration with a recommended adult dosage that provides 23 mg (1 mmol) or more of sodium per dose.

Sodium salts – oral preparations for bowel cleansing

See '[Bowel cleansing oral preparations – sodium salts](#)'

²³ <http://www.tga.gov.au/industry/legislation-tgo.htm>

Soft gel capsules for sedation

Applications for registration of OTC medicines indicated for sedation and presented as soft gel capsules are strongly discouraged on safety grounds, as these products may be subject to abuse by injection, and may be rejected on the grounds of 'unacceptable presentation'.

See ['Antihistamines – use as hypnotics'](#)

Sore throat treatments – antimicrobial

The indications for sore throat treatments (e.g. gargles, sprays and lozenges) containing antimicrobial agents should be restricted to symptomatic relief of sore throat.

Claims that the presence of an antimicrobial agent will reduce the severity or duration of a sore throat are not acceptable unless the sponsor provides appropriate clinical evidence of efficacy for the proposed formulation to substantiate the claim.

Alternatively, if the sponsor wishes to make unsubstantiated antimicrobial, antibacterial or antiseptic claims, the label should include a statement consistent with the following:

- *The presence of the antibacterial/antimicrobial/antiseptic agent in this product has not been shown to have a beneficial effect on the severity or duration of a sore throat.*

Clinical efficacy and safety data (see ARGOM Appendix 1 – *Guideline on efficacy and safety aspects of OTC application*²⁴) will be required to support the registration of any sore throat treatment containing an antimicrobial active ingredient that has not been included as an active ingredient in a product registered on the ARTG. Some examples of substances which have been included in products for relief of sore throats include cetylpyridinium chloride, amylmetacresol, dichlorobenzyl alcohol or benzyl alcohol in lozenges, and povidone iodine in throat gargles.

See also ['Anaesthetic lozenges'](#)

Sympathomimetic amines

See ['Decongestant products, oral'](#)

Teething products

Teething generally occurs in babies between approximately 6-24 months of age. While teething does not generally require medication, oral or topical analgesic products may be useful for relieving pain and discomfort associated with teething.

²⁴ <http://www.tga.gov.au/industry/otc-argom-app1.htm>

Inclusion of relief of pain and discomfort associated with teething in the indications of paediatric oral products containing paracetamol or ibuprofen is acceptable, provided the products comply with the requirements of the respective guidelines on 'Paracetamol' or 'Ibuprofen'.

Topical gel products containing choline salicylate 87 mg/g will be accepted for relief of pain associated with teething, without requiring provision of clinical efficacy or safety data.

Clinical efficacy and safety data will be required to support claims for relief of pain and/or discomfort associated with teething for products containing choline salicylate in any concentration other than 87 mg/g, and/or any other substances (e.g. local anaesthetics), alone or in combination.

See also '[Ibuprofen](#)' and '[Paracetamol](#)'

Tryptophan

Products containing tryptophan will not be approved for indications such as insomnia, anxiety or other depressive illness in the absence of scientific evidence of efficacy and safety. Reports of interactions with antidepressants resulting in adverse effects are further reason for caution.

Urinary alkalinisers

Products intended to produce alkalinisation of the urine should include label warning statements such as:

- *Consult a doctor if pain or irritation persists for more than 48 hours or if you notice blood in your urine.*
- *Do not take this medicine for more than five days unless advised to do so by a doctor.*
- *Do not give this medicine to children under 12 years of age unless advised to do so by a doctor.*
- *Check with a doctor or pharmacist before using this medicine if you are taking other medicines or if you have kidney problems, heart problems or high blood pressure.*

Vaginal itch, topical preparations

Products containing local anaesthetics will not be approved for the topical treatment or relief of vaginal itch.

See also '[Antifungal agents – Use for vaginal candidiasis](#)'

Wart treatments

For products which are indicated for the treatment of warts, the following statements (or similar) should be included on the labels:

- *Do not use if you have diabetes or impaired circulation.*
- *Use only on common warts. Do not use on moles, birthmarks or unusual skin growths. Do not treat warts over large areas at one time.*

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Reference/Publication #