



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|---------|
| Summary for ARTG Entry: | 260023 | Prospan |
| ARTG entry for | Medicine Listed | |
| Sponsor | SFI Australasia | |
| Postal Address | PO Box 1027, CROWS NEST, NSW, 1585 Australia | |
| ARTG Start Date | 16/09/2015 | |
| Product Category | Medicine | |
| Status | Active | |
| Approval Area | Listed Medicines | |

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Prospan

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 28/08/2019 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Anti-inflammatory/relieve inflammation
Decrease/reduce/relieve mild bronchial irritation
Decrease/reduce/relieve mild bronchial irritation in children
Decrease/reduce/relieve bronchial mucous congestion in children
Decrease/reduce/relieve bronchial mucous congestion
Soothe/calm the chest in children
Soothe/calm the chest
Decrease/reduce excess chest phlegm
Decrease/reduce excess chest phlegm in children
Loosen chest phlegm in children
Loosen chest phlegm
Decrease/reduce excess mucous
Decrease/reduce excess mucous in children
Decrease/reduce/relieve mild upper respiratory tract congestion in children
Decrease/reduce/relieve mild upper respiratory tract congestion
Expectorant/clear respiratory tract mucous
Expectorant/clear respiratory tract mucous
Loosen respiratory tract mucous in children
Loosen respiratory tract mucous

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Decrease/reduce/relieve mild bronchial cough in children
 Decrease/reduce/relieve mild bronchial cough
 Decrease/reduce/relieve cough in children
 Decrease/reduce/relieve cough
 Enhance/improve/promote/increase cough productivity
 Enhance/improve/promote/increase cough productivity in children
 Soothe respiratory tract mucous membranes/mucous tissue in children
 Soothe respiratory tract mucous membranes/mucous tissue

Indication Requirements

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
 Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must only refer to mild bronchitis.
 Respiratory tract infections must be qualified by 'mild'.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
 Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--|----------------|
| Hedera helix leaf Extract dry concentrate | 7 mg/mL |
| Equivalent: Hedera helix (Dry) | 43.75 mg/mL |

Other Ingredients (Excipients)

citric acid
 Flavour
 potassium sorbate
 purified water
 sorbitol solution (70 per cent) (crystallising)
 xanthan gum

Public Summary

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