Public Summary

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

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

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.

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 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

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