



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	310596	Thompson's Manuka Mucus Cough Relief Kids
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	22/10/2018	
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.

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 . Thompson's Manuka Mucus Cough Relief Kids

Product Type	Single Medicine Product	Effective Date	22/07/2021
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Permitted Indications

- Antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic in healthy children
- Antispasmodic/spasmolytic in children
- Antispasmodic/spasmolytic in healthy children
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic in children
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion in healthy children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion in children
- Traditionally used in Western herbal medicine to decrease/reduce excess chest phlegm in healthy children
- Traditionally used in Western herbal medicine to decrease/reduce excess chest phlegm
- Traditionally used in Western herbal medicine to decrease/reduce excess chest phlegm in children
- Traditionally used in Western herbal medicine to loosen chest phlegm in children
- Traditionally used in Western herbal medicine to loosen chest phlegm in healthy children
- Traditionally used in Western herbal medicine to loosen chest phlegm
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous in children
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous in healthy children
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous
- Expectorant/clear respiratory tract mucous in healthy children
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in children
- Expectorant/clear respiratory tract mucous
- Expectorant/clear respiratory tract mucous in children
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in healthy children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough in healthy children
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough in children

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Decrease/reduce/relieve cough in healthy children
 Decrease/reduce/relieve cough
 Decrease/reduce/relieve cough in children
 Maintain/support lung health in children
 Traditionally used in Western herbal medicine to maintain/support lung health in healthy children
 Maintain/support lung health
 Traditionally used in Western herbal medicine to maintain/support lung health in children
 Maintain/support lung health in healthy children
 Traditionally used in Western herbal medicine to maintain/support lung health

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
 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.
 Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.
 Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
 Keep out of reach of children (or words to that effect).
 Not suitable for infants under the age of twelve months (or words to that effect).
 (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].
 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.
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Hedera helix leaf Extract liquid	84 microlitre/mL
Equivalent: Hedera helix (Dry)	42 mg/mL
Honey	50 mg/mL

Other Ingredients (Excipients)

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

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