



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321825	Manuka Honey Dry Cough
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	15/08/2019	
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 . Manuka Honey Dry Cough

Product Type	Single Medicine Product	Effective Date	30/08/2024
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body in children
Helps reduce/decrease free radical damage to body cells in children
Maintain/support healthy eye function in children
Maintain/support eye health in children
Maintain/support healthy eyesight/vision in children
Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration in children
Maintain/support healthy growth and development in children
Maintain/support body mucous membrane health in children
Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing in children
Maintain/support general health and wellbeing when sun exposure is inadequate in children
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing in children
Maintain/support general health and wellbeing in children
Maintain/support hair health in children
Aids/assists teeth development in children
Maintain/support healthy teeth in children
Maintain/support teeth mineralisation in children
Maintain/support teeth strength in children
Maintain/support nail health/strength/thickness in children
Maintain/support bone health in children
Aids/assists healthy bone development/growth/building in children
Maintain/support bone strength in children
Help maintain/support bone mineralisation in children
Maintain/support immune system health in children
Traditionally used in Western herbal medicine to maintain/support immune system health in children
Maintain/support healthy immune system function in children
Traditionally used in Western herbal medicine to maintain/support healthy immune system function in children
Maintain/support muscle function in children



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Maintain/support healthy neuromuscular system/function in children
Aid/assist/helps protein synthesis in the body in children
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in children
Maintain/support cognitive function/mental function in healthy children
Maintain/support nerve conduction in children
Maintain/support nervous system function in children
Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial irritation in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children
Traditionally used in Western herbal medicine to relieve dry unproductive cough in children
Traditionally used in Homoeopathic medicine to relieve dry unproductive cough in children
Traditionally used in Western herbal medicine to soothe respiratory tract mucous membranes/mucous tissue in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve throat irritation in children
Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis in children
Maintain/support skin health in children
Maintain/support skin integrity/structure in children
Maintain/support skin regeneration in children
Maintain/support wound healing in children

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must only refer to mild bronchitis.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

Not suitable for infants under the age of twelve months (or words to that effect).

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

Contains homoeopathic ingredients.

(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].

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		
Althaea officinalis root Extract dry concentrate		50 mg/mL
Equivalent: Althaea officinalis (Dry)		200 mg/mL
betacarotene		.15 mg/mL
Bryonia alba root (Homeopathic)		5 microlitre/mL
colecalfiferol		.216 microgram/mL
Honey		60 mg/mL
Honey		250 mg/mL
Rumex crispus root (Homeopathic)		5 microlitre/mL
Sambucus nigra flower Extract dry concentrate		41.66 mg/mL
Equivalent: Sambucus nigra (Dry)		250 mg/mL
zinc glycinate		416 microgram/mL
Equivalent: zinc		127 microgram/mL
Other Ingredients (Excipients)		
dl-alpha-tocopherol		
ethanol		
Flavour		
glycerol		
maize starch		
maltodextrin		
methyl hydroxybenzoate		
modified food starch		
propyl hydroxybenzoate		
purified water		
silicon dioxide		
vegetable oil		
xanthan gum		

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