



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321824	Manuka Honey Chesty 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 Chesty Cough

Product Type	Single Medicine Product	Effective Date	29/07/2022
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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
- Traditionally used in Homoeopathic medicine to relieve feelings of general malaise/general debility in children
- Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness in children
- Maintain/support healthy eye function in children
- Maintain/support eye health in children
- Maintain/support healthy eyesight/vision in children
- Maintain/support healthy growth and development in children
- Maintain/support body mucous membrane health in children
- Maintain/support general health and wellbeing when sun exposure is inadequate in children
- Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing in children
- Traditionally used in Western herbal medicine to 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
- Maintain/support healthy immune system function in children
- Maintain/support muscle function in children
- Maintain/support healthy neuromuscular system/function in children

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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
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy 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 Homoeopathic medicine to decrease/reduce/relieve sleeplessness in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep in children
Traditionally used in Homoeopathic 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 Homoeopathic medicine to decrease/reduce/relieve bronchial mucous congestion in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion in children
Traditionally used in Homoeopathic medicine to soothe/calm the chest in children
Traditionally used in Western herbal medicine to decrease/reduce excess chest phlegm in children
Traditionally used in Homoeopathic medicine to decrease/reduce excess chest phlegm in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of head cold in children
Traditionally used in Western herbal medicine to loosen chest phlegm in children
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Traditionally used in Homoeopathic medicine to decrease/reduce excess mucous in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in children
Traditionally used in Homoeopathic medicine to expectorant/clear respiratory tract mucous in children
Traditionally used in Western herbal medicine to loosen respiratory tract mucous in children
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Traditionally used in Western herbal medicine to enhance/improve/promote/increase cough productivity in children
Traditionally used in Homoeopathic medicine to soothe respiratory tract mucous membranes/mucous tissue in children
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Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of laryngitis in children
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Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation in children
Traditionally used in Homoeopathic 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
Antioxidant/Reduce free radicals formed in the body in children
Helps reduce/decrease free radical damage to body cells in children
Traditionally used in Homoeopathic medicine to relieve feelings of general malaise/general debility in children
Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness in children
Maintain/support healthy eye function in children
Maintain/support eye health in children
Maintain/support healthy eyesight/vision in children
Maintain/support healthy growth and development in children
Maintain/support body mucous membrane health in children
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing in children

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Maintain/support general health and wellbeing 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
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
Maintain/support healthy immune system function in children
Maintain/support muscle function in children
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
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy in children
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Maintain/support nerve conduction in children
Maintain/support nervous system function in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep in children
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Traditionally used in Western herbal medicine to decrease/reduce excess mucous in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children
Traditionally used in Homoeopathic medicine to expectorant/clear respiratory tract mucous in children
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous in children
Traditionally used in Western herbal medicine to loosen respiratory tract mucous in children
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Traditionally used in Homoeopathic medicine to soothe respiratory tract mucous membranes/mucous tissue in children
Traditionally used in Homoeopathic medicine to relieve runny/dripping nose in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat irritation in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of laryngitis in children



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Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation in children
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation in children
 Traditionally used in Homoeopathic 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

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
 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 mental illnesses, disorders or conditions.
 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 not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to serious immunological diseases.
 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.
 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).
 Respiratory tract infections must be qualified by 'mild'.
 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 vision correction, faults or serious eye disease e.g. macular degeneration.

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.
 (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].
 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.

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

Anemone pulsatilla whole plant (Homeopathic)	5 microlitre/mL
antimony potassium tartrate trihydrate (Homeopathic)	5 microlitre/mL
betacarotene	.18 mg/mL
colecalfiferol	.0002 mg/mL
Drosera rotundifolia MIS flower (Homeopathic)	5 microlitre/mL
Hedera helix leaf Extract dry concentrate	10.937 mg/mL



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Equivalent: Hedera helix (Dry)	43.75 mg/mL
Honey	325 mg/mL
Honey	65 mg/mL
marine sponge (Homeopathic)	5 microlitre/mL
phosphorus (Homeopathic)	5 microlitre/mL
zinc glycinate	.71 mg/mL
Equivalent: zinc	.2 mg/mL

Other Ingredients (Excipients)

- dl-alpha-tocopherol**
- ethanol**
- Flavour**
- glycerol**
- maize starch**
- methyl hydroxybenzoate**
- modified food starch**
- propyl hydroxybenzoate**
- purified water**
- silicon dioxide**
- vegetable oil**
- xanthan gum**

2 . Manuka Honey Chesty Cough

Product Type	Single Medicine Product	Effective Date	29/07/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body in children
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- Maintain/support healthy eyesight/vision in children
- Maintain/support healthy growth and development in children
- Maintain/support body mucous membrane health in children
- Maintain/support general health and wellbeing when sun exposure is inadequate in children
- Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing in children
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing in children
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- 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
- Maintain/support healthy immune system function in children
- Maintain/support muscle function in children
- Maintain/support healthy neuromuscular system/function in children
- Aid/assist/helps protein synthesis in the body in children



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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
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Maintain/support skin regeneration in children
Maintain/support wound healing in children
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 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 mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
 Respiratory tract infections must be qualified by 'mild'.
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 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.
 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).
 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 chronic fatigue syndrome.
 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 serious musculoskeletal or neurological conditions.
 Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.
 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].
 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.

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

Anemone pulsatilla whole plant (Homeopathic)	5 microlitre/mL
antimony potassium tartrate trihydrate (Homeopathic)	5 microlitre/mL
betacarotene	.18 mg/mL
colecalfiferol	.0002 mg/mL
Drosera rotundifolia MIS flower (Homeopathic)	5 microlitre/mL
Hedera helix leaf Extract dry concentrate	10.937 mg/mL
Equivalent: Hedera helix (Dry)	43.75 mg/mL

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Honey	325 mg/mL
Honey	65 mg/mL
marine sponge (Homeopathic)	5 microlitre/mL
phosphorus (Homeopathic)	5 microlitre/mL
zinc glycinate	.71 mg/mL
Equivalent: zinc	.2 mg/mL

Other Ingredients (Excipients)

- dl-alpha-tocopherol
- ethanol
- Flavour
- glycerol
- maize starch
- methyl hydroxybenzoate
- modified food starch
- propyl hydroxybenzoate
- purified water
- silicon dioxide
- vegetable oil
- xanthan gum

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