



**Australian Government**  
**Department of Health**  
**Therapeutic Goods Administration**

## Public Summary

<b>Summary for ARTG Entry:</b>	323755	Baby & Child Cough
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Natural Medicine Pty Ltd	
<b>Postal Address</b>	PO Box 234, TANUNDA, SA, 5352 Australia	
<b>ARTG Start Date</b>	18/09/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

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 . Baby & Child Cough

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/04/2020
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support collagen formation  
Maintain/support healthy eye function  
Maintain/support eye health  
Maintain/support healthy eyesight/vision  
Maintain/support healthy growth and development  
Maintain/support general health and wellbeing when sun exposure is inadequate  
Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing  
Traditionally used in Western herbal medicine to maintain/support general health and wellbeing  
Maintain/support general health and wellbeing  
Maintain/support hair health  
Aids/assists teeth development  
Maintain/support healthy teeth  
Maintain/support teeth mineralisation  
Maintain/support teeth strength  
Maintain/support nail health/strength/thickness  
Maintain/support connective tissue health  
Aid/assist/helps connective tissue production/formation  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
Maintain/support bone strength  
Help maintain/support bone mineralisation



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Maintain/support blood capillary health  
Maintain/support blood vessel health  
Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes  
Traditionally used in Western herbal medicine to decrease/reduce/relieve gastrointestinal pain  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle function  
Maintain/support healthy neuromuscular system/function  
Aid/assist/helps protein synthesis in the body  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy  
Maintain/support cognitive function/mental function in healthy children  
Maintain/support nerve conduction  
Maintain/support nervous system function  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial irritation  
Traditionally used in Western herbal medicine to decrease/reduce/relieve bronchial mucous congestion  
Traditionally used in Homoeopathic medicine to soothe/calm the chest  
Traditionally used in Homoeopathic medicine to soothe/calm the chest  
Traditionally used in Western herbal medicine to decrease/reduce excess chest phlegm  
Traditionally used in Homoeopathic medicine to decrease/reduce excess chest phlegm  
Decrease/reduce/relieve common cold duration  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of head cold  
Traditionally used in Homoeopathic medicine to loosen chest phlegm  
Traditionally used in Western herbal medicine to loosen chest phlegm  
Traditionally used in Western herbal medicine to decrease/reduce excess mucous  
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild upper respiratory tract congestion  
Traditionally used in Western herbal medicine to helps soothe respiratory tract  
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous  
Traditionally used in Homoeopathic medicine to expectorant/clear respiratory tract mucous  
Traditionally used in Western herbal medicine to loosen respiratory tract mucous  
Decrease/reduce/relieve the severity of common cold symptoms  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial cough  
Traditionally used in Western herbal medicine to decrease/reduce/relieve mild bronchial cough  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve cough  
Traditionally used in Western herbal medicine to decrease/reduce/relieve cough  
Traditionally used in Western herbal medicine to relieve dry unproductive cough  
Traditionally used in Western herbal medicine to enhance/improve/promote/increase cough productivity  
Traditionally used in Western herbal medicine to soothe respiratory tract mucous membranes/mucous tissue  
Traditionally used in Homoeopathic medicine to soothe respiratory tract mucous membranes/mucous tissue  
Traditionally used in Homoeopathic medicine to relieve hoarseness of voice  
Traditionally used in Western herbal medicine to decrease/reduce/relieve throat irritation  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat irritation  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of laryngitis  
Traditionally used in Western herbal medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation  
Traditionally used in Homoeopathic medicine to relieve symptoms of sore throat/pharyngitis  
Traditionally used in Western herbal medicine to relieve symptoms of sore throat/pharyngitis  
Maintain/support skin health  
Maintain/support skin integrity/structure  
Maintain/support skin regeneration  
Maintain/support wound healing



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

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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 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.

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 only refer to mild bronchitis.

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

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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 homoeopathic ingredients.

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).

#### 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

<b>Althaea officinalis root Extract dry concentrate</b>	<b>25 mg/mL</b>
Equivalent: Althaea officinalis (Dry)	100 mg/mL
<b>antimony potassium tartrate trihydrate (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>calcium ascorbate dihydrate</b>	<b>18.25 mg/mL</b>
Equivalent: ascorbic acid	15 mg/mL
Equivalent: calcium	1.72 mg/mL
<b>calcium sulfide (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Carapichea ipecacuanha root and rhizome (Homeopathic)</b>	<b>5 microlitre/mL</b>
Equivalent: emetine	0 picogram/mL
<b>colecalfiferol</b>	<b>.25 microgram/mL</b>
<b>Drosera rotundifolia whole plant (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Hedera helix leaf Extract dry concentrate</b>	<b>4.5 mg/mL</b>
Equivalent: Hedera helix (Dry)	18 mg/mL

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**Malpighia glabra fruit Powder standardised**

Equivalent: Malpighia glabra (Fresh)

**10.42 mg/mL**

208.4 mg/mL

**marine sponge (Homeopathic)**

**5 microlitre/mL**

**zinc glycinate**

**1.42 mg/mL**

Equivalent: zinc

400 microgram/mL

**Other Ingredients (Excipients)**

**dl-alpha-tocopherol**

**ethanol**

**Flavour**

**glycerol**

**maltodextrin**

**methyl hydroxybenzoate**

**propyl hydroxybenzoate**

**purified water**

**silicon dioxide**

**vegetable oil**

**xanthan gum**

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