



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	323755	Baby & Child Cough
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	18/09/2019	
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.

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

Product Type	Single Medicine Product	Effective Date	29/04/2020
---------------------	-------------------------	-----------------------	------------

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

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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 Western herbal medicine to decrease/reduce/relieve cough
Traditionally used in Homoeopathic 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 Western herbal medicine to relieve symptoms of sore throat/pharyngitis
Traditionally used in Homoeopathic 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

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Indication Requirements

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

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 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 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 only refer to mild bronchitis.

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 immunological diseases.

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

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

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

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.

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 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.

Contains homeopathic ingredients.

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

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



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Malpighia glabra fruit Powder standardised	10.42 mg/mL
Equivalent: Malpighia glabra (Fresh)	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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary