



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322577	Baby & Child Cold & Flu
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	2/09/2019	
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.

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 Cold & Flu

Product Type	Single Medicine Product	Effective Date	10/08/2022
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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
Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Homoeopathic medicine to relieve eye discomfort
Maintain/support healthy eye function
Maintain/support eye health
Traditionally used in Homoeopathic medicine to relieve itchy eyes
Traditionally used in Homoeopathic medicine to relieve eye redness
Traditionally used in Homoeopathic medicine to relieve eye soreness
Maintain/support healthy eyesight/vision
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve watery eyes/excessive lacrimation
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 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 maintain/support immune system health
Maintain/support immune system health
Traditionally used in Western herbal medicine to maintain/support healthy immune system function
Maintain/support healthy immune system function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle pain/ache/soreness
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle tiredness
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)
Maintain/support cognitive function/mental function in healthy children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild dizziness/vertigo
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial irritation
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 common colds and flu
 Linked indication - Decongestant/relieve nasal congestion
 Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
 Linked indication - Decrease/reduce excess mucous
 Linked indication - Decrease/reduce/relieve sneezing
 Linked indication - Decrease/reduce/relieve chills associated with common cold
 Linked indication - Decrease/reduce/relieve cough
 Linked indication - Enhance/improve/promote/increase cough productivity
 Linked indication - Relieve runny/dripping nose
 Linked indication - Decrease/reduce/relieve throat irritation
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of head cold
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild upper respiratory tract congestion
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis
Decrease/reduce/relieve the severity of common cold symptoms
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve the severity of common cold symptoms
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
 Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration
 Linked indication - Decongestant/relieve nasal congestion
 Linked indication - Decrease/reduce/relieve common cold duration
 Linked indication - Expectorant/clear respiratory tract mucous
 Linked indication - Decrease/reduce/relieve cough
 Linked indication - Soothe respiratory tract mucous membranes/mucous tissue
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common cold
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial cough
Traditionally used in Homoeopathic medicine to relieve hoarseness of voice
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of laryngitis
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



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Indication Requirements

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

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

Respiratory tract infections must be qualified by 'mild'.

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

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 vertigo.

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 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 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 chronic fatigue syndrome.

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

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

Contains homeopathic 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.

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

Allium cepa bulb (Homeopathic)	5 microlitre/mL
Equivalent: Allium cepa	500 picogram/mL
Anemone pulsatilla whole plant (Homeopathic)	5 microlitre/mL
Equivalent: Anemone pulsatilla	.0005 picogram/mL
calcium ascorbate dihydrate	24.33 mg/mL
Equivalent: ascorbic acid	20 mg/mL
Equivalent: calcium	2.29 mg/mL
colecalfiferol	.25 microgram/mL
Echinacea purpurea herb top flowering Extract dry concentrate	13.34 mg/mL
Equivalent: Echinacea purpurea (Dry)	53.36 mg/mL
Euphrasia officinalis whole plant (Homeopathic)	5 microlitre/mL
Equivalent: Euphrasia officinalis	500 picogram/mL



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Gelsemium sempervirens root and rhizome (Homeopathic)	5 microlitre/mL
Equivalent: Gelsemium sempervirens	.0005 picogram/mL
Mentha X piperita herb Extract dry concentrate	13.33 mg/mL
Equivalent: Mentha X piperita (Dry)	66.65 mg/mL
Sambucus nigra flower Extract dry concentrate	22.22 mg/mL
Equivalent: Sambucus nigra (Dry)	133.32 mg/mL
Toxicodendron pubescens twig leafy young (Homeopathic)	5 microlitre/mL
Equivalent: Toxicodendron pubescens	.0005 picogram/mL
zinc glycinate	.67 mg/mL
Equivalent: zinc	.2 mg/mL

Other Ingredients (Excipients)

dl-alpha-tocopherol
ethanol
Flavour
glycerol
methyl hydroxybenzoate
propyl hydroxybenzoate
purified water
vegetable oil
xanthan gum

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