



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	322616	Baby & Child Runny Nose
<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>	3/09/2019	
<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 Runny Nose**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/04/2020
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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 energy levels
- Maintain/support energy production
- 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 soreness
- Maintain/support healthy eyesight/vision
- Traditionally used in Homoeopathic medicine to decrease/relieve watery eyes/excessive lacrimation
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Aid/assist healthy red blood cell production

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Maintain/support blood health  
Helps maintain/support haemoglobin formation/synthesis  
Maintain/support blood capillary health  
Maintain/support blood vessel health  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of hayfever  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Aid/assist/helps protein synthesis 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  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms  
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 sleeplessness Temporarily  
Traditionally used in Homoeopathic medicine to decongestant/relieve nasal congestion  
Traditionally used in Homoeopathic medicine to decrease/reduce excess mucous  
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 Homoeopathic medicine to decrease/reduce/relieve sneezing  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial cough  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve cough  
Traditionally used in Homoeopathic medicine to enhance/improve/promote/increase cough productivity  
Traditionally used in Homoeopathic medicine to relieve runny/dripping nose  
Traditionally used in Homoeopathic medicine to relieve hoarseness of voice  
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 Homoeopathic medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation  
Traditionally used in Homoeopathic medicine to relieve symptoms of sore throat/pharyngitis  
Maintain/support skin health  
Maintain/support skin integrity/structure  
Maintain/support wound healing

#### Indication Requirements

Product presentation must only refer to mild bronchitis.

Product presentation must not imply or refer to chronic fatigue syndrome.

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 serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to serious cardiovascular conditions.

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

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).

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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 not imply or refer to serious immunological diseases.

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

#### Standard Indications



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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.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Allium cepa bulb (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Anemone pulsatilla whole plant (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>betacarotene</b>	<b>240 microgram/mL</b>
Equivalent: vitamin A	20 RE/millilitre
<b>calcium ascorbate dihydrate</b>	<b>4.87 mg/mL</b>
Equivalent: ascorbic acid	4 mg/mL
<b>cyanocobalamin</b>	<b>.06 microgram/mL</b>
<b>Euphrasia officinalis whole plant (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>ferrosferric phosphate (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>potassium dichromate (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>potassium iodide (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>70.63 microgram/mL</b>
Equivalent: pyridoxine	40 microgram/mL
<b>sodium chloride (Homeopathic)</b>	<b>5 microlitre/mL</b>

**Other Ingredients (Excipients)**

- citric acid
- dibasic sodium phosphate dihydrate
- dl-alpha-tocopherol
- ethanol
- Flavour
- glycerol
- maize starch
- methyl hydroxybenzoate
- modified food starch
- propyl hydroxybenzoate
- purified water
- xanthan gum

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