



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322616	Baby & Child Runny Nose
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	3/09/2019	
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 Runny Nose

Product Type	Single Medicine Product	Effective Date	29/07/2022
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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
- 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
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support blood capillary health
- Maintain/support blood vessel health

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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

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.

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 mental illnesses, disorders or 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 chronic fatigue syndrome.

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

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

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

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

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

Public Summary

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