



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

## Public Summary

|                                |  |                         |
|--------------------------------|--|-------------------------|
| <b>Summary for ARTG Entry:</b> | 322577                                     | Baby & Child Cold & Flu |
| <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<br>Australia |                         |
| <b>ARTG Start Date</b>         | 2/09/2019                                  |                         |
| <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.

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 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

### 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
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to 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 - Decrease/reduce/relieve throat mucous membrane irritation/inflammation  
    Linked indication - Decongestant/relieve nasal congestion  
    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**

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: If symptoms persist, talk to your health professional.  
 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 only refer to mild bronchitis.  
 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 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**

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**

|                  |                        |
|------------------|------------------------|
| <b>Pack Size</b> | <b>Poison Schedule</b> |
|------------------|------------------------|

**Components**

1 . Formulation 1

|                                |             |
|--------------------------------|-------------|
| <b>Dosage Form</b>             | Oral Liquid |
| <b>Route of Administration</b> | Oral        |

**Visual Identification**

**Active Ingredients**

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



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