



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 322578 | Baby & Child Immunity Support |
| 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 Immunity Support

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 29/07/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Homoeopathic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Homoeopathic medicine to relieve feelings of general malaise/general debility
- 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 eye soreness
- Maintain/support healthy eyesight/vision
- Maintain/support body mucous membrane health
- Traditionally used in Homoeopathic medicine to restorative tonic
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing when sun exposure is inadequate
- Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing
- Aids/assists teeth development
- Maintain/support healthy teeth
- Maintain/support teeth mineralisation
- Maintain/support teeth strength
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Aids/assists healthy bone development/growth/building in healthy infants
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function

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Maintain/support healthy neuromuscular system/function
 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
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nervous tension/unrest
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms
 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/relieve bronchial mucous 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 sneezing
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve cough
 Traditionally used in Homoeopathic medicine to relieve runny/dripping nose
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild throat inflammation
 Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat irritation
 Traditionally used in Homoeopathic medicine to relieve symptoms of sore throat/pharyngitis
 Maintain/support skin health
 Maintain/support skin integrity/structure

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 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: 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 serious musculoskeletal or neurological conditions.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
 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 immunological diseases.
 Respiratory tract infections must be qualified by 'mild'.
 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).

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.

Additional Product information

Pack Size/Poison information

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|------------------|------------------------|
| Pack Size | Poison Schedule |
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Components

1 . Formulation 1

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|--------------------------------|-------------|
| Dosage Form | Oral Liquid |
| Route of Administration | Oral |



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Visual Identification

Active Ingredients

| | |
|---|--------------------------|
| betacarotene | 225 microgram/mL |
| calcium phosphate (Homeopathic) | 5 microlitre/mL |
| Cinchona officinalis stem bark (Homeopathic) | 5 microlitre/mL |
| Equivalent: Quinidine | 0 microgram/mL |
| Equivalent: quinine | 0 microgram/mL |
| colecalfiferol | .625 microgram/mL |
| colloidal anhydrous silica (Homeopathic) | 5 microlitre/mL |
| dibasic potassium phosphate (Homeopathic) | 5 microlitre/mL |
| ferrosoferric phosphate (Homeopathic) | 5 microlitre/mL |
| Oyster shell (Homeopathic) | 5 microlitre/mL |
| phosphorus (Homeopathic) | 5 microlitre/mL |

Other Ingredients (Excipients)

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

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