

# **Australian Government**

## **Department of Health**

# Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: Baby & Child Immunity Support 322578

ARTG entry for Medicine Listed

Sponsor Brauer Natural Medicine Pty Ltd Postal Address PO Box 234, TANUNDA, SA, 5352

2/09/2019 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

#### 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** Effective Date 29/07/2022 Single Medicine Product

## **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 eve 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**

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

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.

Respiratory tract infections must be qualified by 'mild'.

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.

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 not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to serious musculoskeletal or neurological 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).

## **Standard Indications**

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 homoeopathic ingredients.

# **Additional Product information**

# Pack Size/Poison information

Pack Size Poison Schedule

# Components

1 . Formulation 1

 Dosage Form
 Oral Liquid

 Route of Administration
 Oral

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#### **Visual Identification**

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Active	ınared	iients

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 colecalciferol .625 microgram/mL 5 microlitre/mL colloidal anhydrous silica (Homeopathic) dibasic potassium phosphate (Homeopathic) 5 microlitre/mL ferrosoferric phosphate (Homeopathic) 5 microlitre/mL

# phosphorus (Homeopathic) Other Ingredients (Excipients)

Oyster shell (Homeopathic)

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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5 microlitre/mL

5 microlitre/mL