



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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.

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 Immunity Support

Product Type	Single Medicine Product	Effective Date	9/04/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
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 when sun exposure is inadequate
Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing
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



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Help maintain/support bone mineralisation
 Maintain/support immune system health
 Maintain/support healthy immune system function
 Maintain/support muscle function
 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.
 Label statement: If symptoms persist, talk to your health professional.

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 musculoskeletal or neurological conditions.
 Respiratory tract infections must be qualified by 'mild'.

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 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 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 chronic fatigue syndrome.

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

Pack Size	Poison Schedule
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Components

Public Summary



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1 . Formulation 1

Dosage Form Oral Liquid
Route of Administration Oral

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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