



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	345558	METAGENICS E.N.T. IMMUNE CARE FOR KIDS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	8/10/2020	
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 . METAGENICS E.N.T. IMMUNE CARE FOR KIDS

Product Type	Single Medicine Product	Effective Date	8/10/2020
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Permitted Indications

- Maintain/support healthy immune system function in children over 5 years of age
- Maintain/support healthy immune system function in children over 2 years of age
- Traditionally used in Chinese medicine to decongestant/relieve nasal congestion in children over 5 years of age
- Traditionally used in Chinese medicine to decongestant/relieve nasal congestion in children over 2 years of age
- Traditionally used in Chinese medicine to unblock/clear nasal passages in children over 5 years of age
- Traditionally used in Chinese medicine to unblock/clear nasal passages in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve common cold duration in children over 5 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve common cold duration in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children over 5 years of age
- Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous in children over 2 years of age
- Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous in children over 5 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of common cold symptoms in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of common cold symptoms in children over 5 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common cold in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common cold in children over 5 years of age
- Traditionally used in Chinese medicine to relieve runny/dripping nose in children over 2 years of age
- Traditionally used in Chinese medicine to relieve runny/dripping nose in children over 5 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild throat inflammation in children over 5 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild throat inflammation in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild throat infection in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild throat infection in children over 5 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation in children over 2 years of age
- Traditionally used in Chinese medicine to decrease/reduce/relieve throat mucous membrane irritation/inflammation in children over 5 years of age

Indication Requirements

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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).

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 infections.

Respiratory tract infections must be qualified by 'mild'.

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	69.44 mg/g
Astragalus membranaceus root Extract dry concentrate	208.33 mg/g
Equivalent: Astragalus membranaceus (Dry)	2.08 g/g
colecalfiferol	.0027 mg/g
Ganoderma lucidum fruiting body Extract dry concentrate	49.02 mg/g
Equivalent: Ganoderma lucidum (Dry)	833.34 mg/g
Glycyrrhiza glabra root Extract dry concentrate	23.81 mg/g
Equivalent: Glycyrrhiza glabra (Dry)	166.67 mg/g
Olea europaea leaf Extract dry concentrate	16.67 mg/g
Equivalent: Olea europaea (Dry)	500 mg/g
zinc sulfate monohydrate	6.1 mg/g
Equivalent: zinc	2.22 mg/g

Other Ingredients (Excipients)

- Acacia
- citric acid
- dl-alpha-tocopherol
- Flavour
- maize starch
- maltodextrin
- medium chain triglycerides
- silicon dioxide
- Steviol glycosides
- sucrose
- xylitol

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