



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375612	ETHICAL NUTRIENTS IMMUNE DEFENCE CAPSULES
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	1/10/2021	
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 . ETHICAL NUTRIENTS IMMUNE DEFENCE CAPSULES

Product Type	Single Medicine Product	Effective Date	1/10/2021
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Permitted Indications

- Traditionally used in Chinese medicine to aids/assists with recovery from illness/convalescence
- Aids/assists with recovery from illness/convalescence
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support immune system health
- Traditionally used in Ayurvedic medicine to maintain/support immune system health
- Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity
- Maintain/support healthy immune system function
- Traditionally used in Chinese medicine to maintain/support immune system to fight illness
- Maintain/support immune system to fight illness
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
- Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of common cold symptoms
 - Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Clear/expel/dissolve/resolve Phlegm
- Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of common cold symptoms
- Traditionally used in Chinese medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of common cold
 - Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Clear/expel/dissolve/resolve Phlegm
- Traditionally used in Chinese medicine to relieve symptoms of sore throat/pharyngitis

Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- 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.
- Label statement: If symptoms persist, talk to your health professional.

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Product presentation must not imply or refer to chronic fatigue syndrome.

Label statement: Not to be used in children under 5 years.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Andrographis may cause taste disturbance including loss of taste. If you develop any adverse symptoms, stop use and seek medical advice (or words to that effect).

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.

Andrographis may cause allergic reactions in some people. If you have a severe reaction (such as anaphylaxis), stop use and seek immediate medical attention (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	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Andrographis paniculata whole plant Extract dry concentrate	375 mg
Equivalent: Andrographis paniculata (Dry)	6 g
colecalfiferol	.01 mg
Curcuma longa rhizome Extract dry concentrate	40 mg
Equivalent: Curcuma longa (Dry)	1 g
Echinacea purpurea whole plant Extract dry concentrate	150 mg
Equivalent: Echinacea purpurea (Dry)	1.5 g
Eleutherococcus senticosus root Extract dry concentrate	142.86 mg
Equivalent: Eleutherococcus senticosus (Dry)	2 g
zinc amino acid chelate	60 mg
Equivalent: zinc	12 mg

Other Ingredients (Excipients)

- Acacia
- carmellose
- chlorophyllin-copper complex
- citric acid
- disodium edetate
- dl-alpha-tocopherol
- gellan gum
- hypromellose
- magnesium stearate
- maize starch
- medium chain triglycerides
- potassium acetate
- purified water

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silicon dioxide

sorbitan monolaurate

sucrose

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