



**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  
Maintain/support immune system to fight illness  
Traditionally used in Chinese medicine to 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  
Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of common cold symptoms  
Linked indication - Clear/expel/dissolve/resolve Phlegm  
Linked indication - Decrease/reduce/relieve cough  
Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling  
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 - Decrease/reduce/relieve cough  
Linked indication - Clear/expel/dissolve/resolve Phlegm  
Linked indication - Antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling  
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

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).

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).

#### 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

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