



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	355174	Immunitone Plus
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Designs For Health Pty Ltd	
<b>Postal Address</b>	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
<b>ARTG Start Date</b>	18/02/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Immunitone Plus

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	18/02/2021
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#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Decrease/reduce/relieve common cold duration  
Decrease/reduce/relieve symptoms of common colds and flu

#### Indication Requirements

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Do not take while on warfarin therapy without medical advice.

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).

#### Additional Product information

#### Pack Size/Poison information



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Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Andrographis paniculata leaf Extract dry concentrate standardised</b>	<b>166.67 mg</b>
Equivalent: Andrographis paniculata (Dry)	8.33 g
<b>Astragalus membranaceus root Extract dry concentrate</b>	<b>11.11 mg</b>
Equivalent: Astragalus membranaceus (Dry)	333 mg
<b>Cordyceps sinensis hyphae Extract dry concentrate</b>	<b>16.67 mg</b>
Equivalent: Cordyceps sinensis (Dry)	50 mg
<b>Echinacea purpurea root and rhizome Extract dry concentrate</b>	<b>83.33 mg</b>
Equivalent: Echinacea purpurea (Dry)	500 mg
<b>Ganoderma lucidum fruiting body Powder</b>	<b>16.67 mg</b>
<b>Grifola frondosa fruiting body Powder</b>	<b>16.67 mg</b>
<b>Larix arabinogalactan</b>	<b>33.33 mg</b>
<b>lauric acid</b>	<b>33.33 mg</b>
<b>Lentinula edodes fruiting body Powder</b>	<b>16.67 mg</b>
<b>Sambucus nigra fruit Extract dry concentrate</b>	<b>9.52 mg</b>
Equivalent: Sambucus nigra (Fresh)	333.33 mg
<b>zinc amino acid chelate</b>	<b>75 mg</b>
Equivalent: zinc	15 mg

**Other Ingredients (Excipients)**

hypromellose

magnesium stearate

maltodextrin

purified water

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