Public Summary

Summary for ARTG Entry:	383995 Immunitone Plus
ARTG entry for	Medicine Listed
Sponsor	Designs For Health Pty Ltd
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia
ARTG Start Date	15/02/2022
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 . Immunitone Plus

Product Type Single Medicine Product **Effective Date** 15/02/2022

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

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).

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

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).

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).

Do not take while on warfarin therapy without medical advice.

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Andrographis paniculata leaf Extract dry concentrate standardised	**166.67 mg**
Equivalent: Andrographis paniculata (Dry)	8.33 g
Astragalus membranaceus root Extract dry concentrate	**11.11 mg**
Equivalent: Astragalus membranaceus (Dry)	333 mg
Cordyceps sinensis hyphae Extract dry concentrate	**16.67 mg**
Equivalent: Cordyceps sinensis (Dry)	50 mg
Echinacea purpurea root Extract dry concentrate	**83.33 mg**
Equivalent: Echinacea purpurea (Dry)	500 mg
Ganoderma lucidum fruiting body Powder	**16.67 mg**
Grifola frondosa fruiting body Powder	**16.67 mg**
Larix arabinogalactan	**33.33 mg**
lauric acid	**33.33 mg**
Lentinula edodes fruiting body Powder	**16.67 mg**
Sambucus nigra fruit Extract dry concentrate	**9.52 mg**
Equivalent: Sambucus nigra (Fresh)	333.2 mg
zinc amino acid chelate	**75 mg**
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

magnesium stearate

purified water