

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 408265 My Immune Support

ARTG entry for Medicine Listed

Sponsor Thera Health Pty Ltd

Postal Address 18/93 Rivergate Place, Murarrie, QLD, 4172

Australia

ARTG Start Date 1/05/2023

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. My Immune Support

Product Type Single Medicine Product Effective Date 1/05/2023

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support general health and wellbeing

Anti-inflammatory/relieve inflammation

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Helps reduce occurrence of symptoms of upper respiratory tract infections

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: 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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

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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration O

Visual Identification

Active Ingredients

| ascorbic acid | 125 mg |
|---|----------------|
| Astragalus membranaceus root Extract dry concentrate | 100 mg |
| Equivalent: Astragalus membranaceus (Dry) | 1.5 g |
| Ganoderma lucidum fruiting body Extract dry concentrate | 14.3 mg |
| Equivalent: Ganoderma lucidum (Dry) | 500 mg |
| Lentinula edodes fruiting body Extract dry concentrate | 50 mg |
| Equivalent: Lentinula edodes (Dry) | 500 mg |
| Schisandra chinensis fruit Extract dry concentrate | 50 mg |
| Equivalent: Schisandra chinensis (Dry) | 250 mg |
| selenomethionine | 31 microgram |
| Equivalent: selenium | 12.5 microgram |
| Trametes versicolor whole plant Extract dry concentrate | 25 mg |

Trametes versicolor whole plant Extract dry concentrate
Equivalent: Trametes versicolor (Dry)
250 mg
Withania somnifera root Extract dry concentrate
Equivalent: Withania somnifera (Dry)
600 mg
zinc citrate dihydrate
Equivalent: zinc
7.5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose leucine

maltodextrin

microcrystalline cellulose

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