



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	408266	My Immune Cold + Flu
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 Cold + Flu

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

Aids/assists with recovery from illness/convalescence
Maintain/support general health and wellbeing
Enhance/improve/promote immune defence/immunity
Maintain/support healthy immune system function
Helps stimulate a healthy immune system response
Helps reduce occurrence of common colds
Decrease/reduce/relieve common cold duration
Helps decrease/reduce/relieve the severity of symptoms of common colds and flu
Decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Decrease/reduce/relieve the severity of common cold symptoms
Helps reduce occurrence of symptoms of upper respiratory tract infections
Decrease/reduce/relieve cough
Helps decrease/reduce occurrence of sore throat

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
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.
Respiratory tract infections must be qualified by 'mild'.
Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (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).

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

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	160 mg
Equivalent: Andrographis paniculata (Dry)	8 g
ascorbic acid	100 mg
Echinacea purpurea root Extract dry concentrate	150 mg
Equivalent: Echinacea purpurea (Dry)	900 mg
Lonicera japonica flower Extract dry concentrate	50 mg
Equivalent: Lonicera japonica (Dry)	500 mg
Magnolia officinalis stem bark Extract dry concentrate	30 mg
Equivalent: Magnolia officinalis (Dry)	300 mg
Platycodon grandiflorus root Extract dry concentrate	50 mg
Equivalent: Platycodon grandiflorus (Dry)	500 mg
Sambucus nigra fruit Extract dry concentrate	80 mg
Equivalent: Sambucus nigra (Dry)	2.8 g
zinc citrate dihydrate	15.6 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
leucine
maltodextrin
microcrystalline cellulose

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