



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	381172	Thompson's Immune Protect tablet
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	21/12/2021	
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 . Thompson's Immune Protect tablet

Product Type	Single Medicine Product	Effective Date	5/12/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Traditionally used in Chinese medicine to clear/expel dampness to resolve/eliminate the phlegm
Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
Traditionally used in Chinese medicine to aids/assists with recovery from illness/convalescence
Maintain/support general health and wellbeing
Maintain/support immune system health
Traditionally used in Western herbal medicine to maintain/support immune system health
Helps enhance/improve/promote immune system function
Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
Traditionally used in Western herbal medicine to maintain/support healthy immune system function
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
Traditionally used in Western herbal medicine to helps stimulate a healthy immune system response
Helps stimulate a healthy immune system response
Traditionally used in Chinese medicine to decrease/reduce/relieve cough

Indication Requirements

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.

Product presentation must not imply or refer to serious immunological diseases.

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.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications



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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

If symptoms persist consult your healthcare practitioner (or words to that effect).

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

Astragalus membranaceus root Extract dry concentrate	200 mg
Equivalent: Astragalus membranaceus (Dry)	1 g
Ganoderma lucidum mushroom Extract dry concentrate	50 mg
Equivalent: Ganoderma lucidum (Dry)	500 mg
Ligustrum lucidum fruit Extract dry concentrate	50 mg
Equivalent: Ligustrum lucidum (Dry)	500 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
hypromellose
iron oxide black
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
sodium starch glycollate
vanillin

Public Summary

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