



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	312049	ImmunoAdapt
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	29/11/2018	
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 . ImmunoAdapt

Product Type	Single Medicine Product	Effective Date	25/02/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Chinese medicine to clear/expel dampness to resolve/eliminate the phlegm
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Ayurvedic medicine to enhance/promote energy levels
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Chinese medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence in elderly individuals
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility in elderly individuals
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Traditionally used in Ayurvedic medicine to longevity tonic
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Maintain/support immune system health
- Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to 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
- Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms
 - Linked indication - Relieve feelings of general malaise/general debility
 - Linked indication - Decrease/reduce/relieve mild upper respiratory tract congestion
 - Linked indication - Decrease/reduce/relieve sneezing
 - Linked indication - Decrease/reduce/relieve cough
 - Linked indication - Relieve runny/dripping nose
 - Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation
- Traditionally used in Western herbal medicine to relieve symptoms of mild upper respiratory tract infections

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Traditionally used in Chinese medicine to decrease/reduce/relieve cough

Indication Requirements

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

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 chronic fatigue syndrome.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

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 serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Respiratory tract infections must be qualified by 'mild'.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

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

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Astragalus membranaceus root Extract dry concentrate	100 mg
Equivalent: Astragalus membranaceus (Dry)	500 mg
Echinacea purpurea root Extract liquid	1 mL
Equivalent: Echinacea purpurea (Dry)	500 mg
Ganoderma lucidum fruiting body Extract dry concentrate	37.5 mg
Equivalent: Ganoderma lucidum (Dry)	375 mg
Lentinula edodes fruiting body Extract dry concentrate	93.75 mg
Equivalent: Lentinula edodes (Dry)	375 mg
Withania somnifera root Extract dry concentrate standardised	75 mg
Equivalent: Withania somnifera (Dry)	750 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- croscarmellose sodium
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose

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