



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|---------------------|
| Summary for ARTG Entry: | 386663 | Eagle Defence Adapt |
| 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 | 3/04/2022 11:00:00 PM | |
| 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 . Eagle Defence Adapt

| Product Type | Single Medicine Product | Effective Date | 4/04/2022 |
|--------------|-------------------------|----------------|-----------|
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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 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 Ayurvedic medicine to aids/assists with recovery from illness/convalescence in elderly individuals
- Traditionally used in Chinese medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility in elderly individuals
- 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
- 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
- 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

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

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.

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.

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

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

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'.

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

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| 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 | 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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