

## **Australian Government**

## **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 334708 Eagle Defence Support Tablets

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
 21/04/2020

 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 Support Tablets

Product Type Single Medicine Product Effective Date 23/04/2025

## Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral) within normal range

### Indication Requirements

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

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

### **Standard Indications**

No Standard Indications included on Record

## **Specific Indications**

No Specific Indications included on Record

### Warnings

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

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).

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

For practitioner dispensing only.

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 Tablet, film coated

Route of Administration Oral

Visual Identification

### **Active Ingredients**

Andrographis paniculata leaf Extract dry concentrate standardised	214.3 mg
Equivalent: Andrographis paniculata (Dry)	ū
Equivalent. Andrographis particulata (Dry)	3000.2 mg
ascorbic acid	250 mg
Citrus bioflavonoids extract	50 mg
colecalciferol	.005 mg
Ganoderma lucidum fruiting body Extract dry concentrate	75 mg
Equivalent: Ganoderma lucidum (Dry)	750 mg
retinol acetate	.1414 mg
Equivalent: vitamin A	.1199 mg
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

## Other Ingredients (Excipients)

## Acacia

calcium carbonate

calcium hydrogen phosphate dihydrate

croscarmellose sodium

dl-alpha-tocopherol

hydrogenated soya oil

hydrolysed gelatin

hypromellose

magnesium stearate

maize starch

maltodextrin

microcrystalline cellulose

povidone

silicon dioxide

spray-dried glucose syrup

sucrose

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