



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|----------------|
| Summary for ARTG Entry: | 333906 | Eagle ACU-Mind |
| 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 | 10/04/2020 | |
| 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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27) as in force or existing from time to time. This condition does not apply to powdered or dried leaf.

Products

1 . Eagle ACU-Mind

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 26/03/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to cardi tonic/strengthen heart
- Support healthy stress response in the body
- Helps enhance/improve/promote/increase attention span
- Helps enhance/improve/promote/increase attention span in individuals over 50 years
- Enhance/improve/promote/increase cognitive performance
- Enhance/improve/promote/increase cognitive performance in individuals over 50 years
- Maintain/support cognitive function/mental function
- Enhance/improve/promote learning ability/function in individuals over 50 years
- Enhance/improve/promote learning ability/function
- Enhance/improve/promote/increase memory/recall in individuals over 50 years
- Enhance/improve/promote/increase memory/recall
- Traditionally used in Ayurvedic medicine to brain tonic/Enhance brain health
- Traditionally used in Ayurvedic medicine to nerve tonic

Indication Requirements

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

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

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

| | |
|---|----------------|
| Bacopa monnieri whole plant Extract dry concentrate | 225 mg |
| Equivalent: Bacopa monnieri (Dry) | 4500 mg |
| colecalfiferol | .005 mg |
| Ginkgo biloba leaf Dry | 60 mg |
| Equivalent: Ginkgo biloba (Dry) | 3000 mg |
| Rhodiola rosea root Extract dry concentrate standardised | 170 mg |
| Equivalent: Rhodiola rosea (Dry) | 680 mg |

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
hydrogenated soya oil
hydrolysed gelatin
hypromellose
magnesium stearate
maize starch
microcrystalline cellulose
silicon dioxide
sucrose

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