



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	337391	Eagle NeuroMood
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	3/06/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 NeuroMood

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	24/01/2022
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### Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range
- Help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Decrease/reduce/relieve symptoms of mild anxiety
- Helps reduce occurrence of symptoms of mild anxiety
- Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety
- Aid/assist/helps synthesis of neurotransmitters
- Traditionally used in Western herbal medicine to maintain/support nervous system health
- Support healthy emotional/mood balance
- Traditionally used in Western herbal medicine to support healthy emotional/mood balance

### Indication Requirements

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

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

Product presentation must only refer to mild anxiety.

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).

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### Standard Indications

No Standard Indications included on Record

### Specific Indications



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No Specific Indications included on Record

#### Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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.

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

For practitioner dispensing only.

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

<b>Crocus sativus stigma Extract dry concentrate</b>	<b>17.5 mg</b>
Equivalent: Crocus sativus (Dry)	53 mg
<b>Hypericum perforatum herb top flowering Extract dry concentrate standardised</b>	<b>416.7 mg</b>
Equivalent: Hypericum perforatum (Dry)	2.5 g
<b>levomefolate calcium</b>	<b>216 microgram</b>
Equivalent: levomefolic acid	200 microgram
<b>mecobalamin (co-methylcobalamin)</b>	<b>75 microgram</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>31.4 mg</b>
Equivalent: pyridoxine	20 mg
<b>tyrosine</b>	<b>250 mg</b>
<b>zinc amino acid chelate</b>	<b>60 mg</b>
Equivalent: zinc	12 mg

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate  
chlorophyllin-copper complex  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
dextrin  
hypromellose  
macrogol 3350  
magnesium stearate  
maltodextrin  
microcrystalline cellulose

Public Summary

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