Public Summary

Summary for ARTG Entry:	279783 Eagle NeuroMood
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	31/08/2016
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

Product Type	Single Medicine Product	**Effective Date**	3/06/2019

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

Traditionally used in Western herbal medicine to support healthy emotional/mood balance

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.

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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

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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.

If symptoms persist consult your healthcare practitioner (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

Crocus sativus	**15.75 mg**
Hypericum perforatum herb top flowering Extract dry concentrate standardised	**409.09 mg**
Equivalent: Hypericum perforatum (Dry)	2.454 g
levomefolate calcium	**216.57 microgram**
Equivalent: levomefolic acid	200 microgram
mecobalamin (co-methylcobalamin)	**75 microgram**
pyridoxal 5-phosphate monohydrate	**31.35 mg**
Equivalent: pyridoxine	20 mg
tyrosine	**250 mg**
zinc citrate dihydrate	**37.38 mg**
Equivalent: zinc	12 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dextrin
hypromellose
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
soy polysaccharide

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