

# **Australian Government**

# **Department of Health**

# Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 392811 Mood, Memory & Libido Support

ARTG entry for Medicine Listed

Sponsor NRC Nutrition Pty Ltd

Postal Address PO Box 1248, Coolum Beach, QLD, 4573

26/07/2022 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

#### 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. Mood, Memory & Libido Support

**Product Type** Effective Date 26/07/2022 Single Medicine Product

# **Permitted Indications**

Traditionally used in Western herbal medicine to maintain/support physical endurance/capacity/stamina

Traditionally used in Western herbal medicine to helps enhance/promote healthy blood circulation

Traditionally used in Western herbal medicine to helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet)

Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress

Helps enhance/improve/promote/increase attention span

Enhance/improve/promote/increase cognitive performance

Maintain/support cognitive function/mental function

Enhance/improve/promote/increase memory/recall

Maintain/support memory/mental recall

Enhance/improve/promote/increase short term memory

Traditionally used in Western herbal medicine to nervine/support nervous system

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

Maintain/support preconception health

Aphrodisiac/Enhance/improve/promote healthy libido

Maintain/support healthy sexual function

### **Indication Requirements**

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

Product presentation must not imply or refer to serious cardiovascular conditions.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Product presentation must not imply or refer to infertility.

### Standard Indications

No Standard Indications included on Record

# **Specific Indications**

No Specific Indications included on Record

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No Warnings included on Record

### **Additional Product information**

### Pack Size/Poison information

Pack Size Poison Schedule

### Components

### 1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

### **Active Ingredients**

Bacopa monnieri whole plant Extract dry concentrate standardised	200 mg
Equivalent: Bacopa monnieri (Dry)	4000 mg
Eleutherococcus senticosus root and rhizome Extract dry concentrate	133.33 mg
Equivalent: Eleutherococcus senticosus (Dry)	2 g
Ginkgo biloba leaf Extract dry concentrate	100 mg
Equivalent: Ginkgo biloba (Dry)	5 g
Tribulus terrestris leaf Extract dry concentrate	230 mg
Equivalent: Tribulus terrestris (Dry)	11.5 g
Turnera diffusa leaf Extract dry concentrate	50 mg
Equivalent: Turnera diffusa (Dry)	1.25 g

# Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

edetic acid gellan gum hypromellose maltodextrin

medium chain triglycerides microcrystalline cellulose

potable water potassium acetate

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