



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	386333	Stress & Sleep PM Formula
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregian Beach, QLD, 4573 Australia	
ARTG Start Date	28/03/2022	
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 . Stress & Sleep PM Formula

Product Type	Single Medicine Product	Effective Date	28/03/2022
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Permitted Indications

- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant
- Traditionally used in Western herbal medicine to nervine/support nervous system
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Western herbal medicine to enhance/promote/increase healthy sleep patterns
- Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Crocus sativus stigma Dry	2.997 mg
Equivalent: Crocus sativus (Dry)	9.99 mg
Lavender Oil	40 mg
Matricaria chamomilla flower Extract dry concentrate	112.5 mg
Equivalent: Matricaria chamomilla (Dry)	900 mg
Passiflora incarnata herb Extract dry concentrate	25 mg
Equivalent: Passiflora incarnata (Dry)	1.25 g
Withania somnifera root Extract dry concentrate	112.5 mg
Equivalent: Withania somnifera (Dry)	2.25 g

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
dextrin
hypromellose
maltodextrin
microcrystalline cellulose
potable water

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