



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	410382	Menopause Night Formula
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregrine Beach, QLD, 4573 Australia	
ARTG Start Date	13/06/2023	
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 . Menopause Night Formula

Product Type	Single Medicine Product	Effective Date	13/06/2023
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Permitted Indications

Traditionally used in Western herbal medicine to soporific/induces sleep

Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep

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 helps decrease/reduce/relieve night sweats associated with menopause

Maintain/support oestrogen hormone levels

Traditionally used in Western herbal medicine to maintain/support healthy reproductive hormones

Indication Requirements

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

Product presentation must not imply or refer to hormone imbalances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1



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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Humulus lupulus flower Extract dry concentrate	94.67 mg
Equivalent: Humulus lupulus (Dry)	710 mg
Salvia officinalis leaf Extract dry concentrate standardised	90 mg
Equivalent: Salvia officinalis (Dry)	900 mg
Valeriana officinalis root Extract dry concentrate	175 mg
Equivalent: Valeriana officinalis (Dry)	1.75 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	66.67 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	2 g

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
maltodextrin
microcrystalline cellulose
potable water
potassium acetate

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