



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	410381	Menopause Day Formula
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 380, Peregrine Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	13/06/2023	
<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 . Menopause Day Formula

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	13/06/2023
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### Permitted Indications

Traditionally used in Western herbal medicine to maintain/support adrenal gland health  
Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function  
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress  
Traditionally used in Western herbal medicine to nervine/support nervous system  
Traditionally used in Western herbal medicine to support healthy emotional/mood balance  
Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause  
Traditionally used in Western herbal medicine to decrease/reduce/relieve aggression/irritability associated with menopause  
Traditionally used in Western herbal medicine to decrease/reduce/relieve moodiness/mood swings 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 any adrenal related diseases.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
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

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.  
Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

### Additional Product information



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Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Actaea racemosa root and rhizome Extract dry concentrate	66.67 mg
Equivalent: Actaea racemosa (Dry)	200 mg
Asparagus racemosus root peel Extract dry concentrate	120 mg
Equivalent: Asparagus racemosus (Dry)	1.2 g
Crocus sativus stigma Dry	4.203 mg
Equivalent: Crocus sativus (Dry)	14.01 mg
Hypericum perforatum herb Extract dry concentrate	300 mg
Equivalent: Hypericum perforatum (Dry)	1.8 g
Rehmannia glutinosa root Extract dry concentrate	90 mg
Equivalent: Rehmannia glutinosa (Dry)	900 mg
Trifolium pratense herb Extract dry	200 mg
Equivalent: Trifolium pratense (Fresh)	200 mg
Other Ingredients (Excipients)	
ascorbyl palmitate	
calcium hydrogen phosphate dihydrate	
colloidal anhydrous silica	
dextrin	
edetic acid	
gellan gum	
hypromellose	
maltodextrin	
microcrystalline cellulose	
potable water	
potassium acetate	
silicon dioxide	

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