



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	413835	Preconception Stress & EstroSupport
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregian Beach, QLD, 4573 Australia	
ARTG Start Date	20/07/2023	
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 . Preconception Stress & EstroSupport

Product Type	Single Medicine Product	Effective Date	20/07/2023
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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 Ayurvedic medicine to maintain/support female reproductive system health
- Maintain/support oestrogen hormone levels
- Traditionally used in Ayurvedic medicine to helps enhance/promote preconception health
- Traditionally used in Western herbal medicine to maintain/support healthy reproductive hormones
- Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido
- Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function

Indication Requirements

- Product presentation must not imply or refer to hormone imbalances.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to infertility.
- Product presentation must not imply or refer to any adrenal related diseases.
- If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

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St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

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

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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