# Public Summary

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| **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<br>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

#### 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 mental illnesses, disorders or 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 hormone imbalances.
Product presentation must not imply or refer to any adrenal related diseases.
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

#### 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.

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 |
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**Components**

**1 . Formulation 1**

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| **Dosage Form** | Capsule, hard |
| **Route of Administration** | Oral |
| **Visual Identification** | |

**Active Ingredients**

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| **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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