



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	384490	PMS Support & Antioxidant
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregian Beach, QLD, 4573 Australia	
ARTG Start Date	22/02/2022	
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 . PMS Support & Antioxidant

Product Type	Single Medicine Product	Effective Date	1/04/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support female healthy hormonal balance

Traditionally used in Western herbal medicine to maintain/support female reproductive system health

Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Traditionally used in Western herbal medicine to maintain/support/regulate healthy menstrual cycle

Traditionally used in Western herbal medicine to decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of premenstrual tension

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

Maintain/support skin health

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.

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

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

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

Crocus sativus stigma Dry	1.503 mg
Equivalent: Crocus sativus (Dry)	5.01 mg
Punica granatum fruit peel Extract dry concentrate	10 mg
Equivalent: Punica granatum (Dry)	500 mg
Rosmarinus officinalis leaf Extract dry concentrate	150 mg
Equivalent: Rosmarinus officinalis (Dry)	1.5 g
Vitex agnus-castus fruit Extract dry concentrate	150 mg
Equivalent: Vitex agnus-castus (Dry)	1.5 g
Vitis vinifera seed Extract dry concentrate	50 mg
Equivalent: Vitis vinifera (Dry)	6 g
zinc citrate dihydrate	77.88 mg
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

ascorbyl palmitate

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

dextrin

hypromellose

maltodextrin

microcrystalline cellulose

purified water

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