



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|----------------------|
| Summary for ARTG Entry: | 383362 | Cycle & Skin Support |
| ARTG entry for | Medicine Listed | |
| Sponsor | NRC Nutrition Pty Ltd | |
| Postal Address | PO Box 1248, Coolumb Beach, QLD, 4573 Australia | |
| ARTG Start Date | 2/02/2022 | |
| 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 . Cycle & Skin Support

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 7/07/2022 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
Traditionally used in Ayurvedic medicine to aid/assist/helps in the management of sugar cravings
Traditionally used in Western herbal medicine to uterine tonic/Enhance uterine health
Traditionally used in Western herbal medicine to haemagogue/emmenagogue/promotes menstrual flow
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 menstruation pain/dysmenorrhoea
Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of acne

Indication Requirements

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must only refer to detoxification in relation to natural body processes.
If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
Product presentation must not imply or refer to abortifacient action.
Product presentation must not imply or refer to drugs/alcohol.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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 | |
| Angelica polymorpha root Extract dry concentrate | 66.67 mg |
| Equivalent: Angelica polymorpha (Dry) | 1 g |
| Arctium lappa root Extract dry concentrate | 16.67 mg |
| Equivalent: Arctium lappa (Dry) | 333.33 mg |
| Glycyrrhiza glabra rhizome Extract dry concentrate | 64.1 mg |
| Equivalent: Glycyrrhiza glabra (Dry) | 833.33 mg |
| Gymnema sylvestre leaf Extract dry concentrate | 166.67 mg |
| Equivalent: Gymnema sylvestre (Dry) | 3.33 g |
| inositol | 166.67 mg |
| Paenonia lactiflora root Extract dry concentrate | 142.86 mg |
| Equivalent: Paenonia lactiflora (Dry) | 1 g |
| Urtica dioica leaf Extract dry concentrate | 83.33 mg |
| Equivalent: Urtica dioica (Dry) | 833.33 mg |
| Other Ingredients (Excipients) | |
| ascorbyl palmitate | |
| calcium hydrogen phosphate dihydrate | |
| colloidal anhydrous silica | |
| edetic acid | |
| gellan gum | |
| hypromellose | |
| maltodextrin | |
| microcrystalline cellulose | |
| potable water | |
| potassium acetate | |

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