



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	383361	Lactation Support
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregian 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 . Lactation Support

Product Type	Single Medicine Product	Effective Date	2/02/2022
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Permitted Indications

Traditionally used in Western herbal medicine to nervine/support nervous system

Traditionally used in Western herbal medicine to galactagogue/lactagogue/Enhance/improve/promote/increase breast milk production

Traditionally used in Western herbal medicine to maintain/support breast milk production/lactation

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

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

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Galega officinalis herb Extract dry concentrate	62.5 mg
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Equivalent: Galega officinalis (Dry)	1.25 g
Trigonella foenum-graecum seed Extract dry concentrate	6 mg
Equivalent: Trigonella foenum-graecum (Dry)	750 mg
Urtica dioica leaf Extract dry concentrate	125 mg
Equivalent: Urtica dioica (Dry)	1.25 g
Verbena officinalis herb Extract dry concentrate	66.67 mg
Equivalent: Verbena officinalis (Dry)	1 g

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
maltodextrin
microcrystalline cellulose
purified water

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