



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	383361	Lactation Support
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 1248, Coolum Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	2/02/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/02/2022
---------------------	-------------------------	-----------------------	-----------

#### 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

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

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

#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

<b>Galega officinalis herb Extract dry concentrate</b>	<b>62.5 mg</b>
--	----------------

Public Summary



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

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

**Other Ingredients (Excipients)**

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary