



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	383360	Birth Prep & Recovery
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 . Birth Prep & Recovery

Product Type	Single Medicine Product	Effective Date	15/02/2022
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Permitted Indications

- Traditionally used in Western herbal medicine to astringent/tightens tissues
- Traditionally used in Western herbal medicine to uterine tonic/Enhance uterine health
- Traditionally used in Western herbal medicine to helps prepare the body for labour
- Traditionally used in Western herbal medicine to aid/assist prepare uterus for childbirth

Indication Requirements

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Mitchella repens herb Extract dry concentrate	62.5 mg
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Equivalent: <i>Mitchella repens</i> (Dry)	1.25 g
Rubus idaeus leaf Extract dry concentrate	300 mg
Equivalent: <i>Rubus idaeus</i> (Dry)	1.2 g

Other Ingredients (Excipients)

ascorbyl palmitate

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

maltodextrin

microcrystalline cellulose

purified water

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