Public Summary

Summary for ARTG Entry:	373054 Progest Fortify
ARTG entry for	Medicine Listed
Sponsor	RN Labs Pty Ltd
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia
ARTG Start Date	18/08/2021
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 . Progest Fortify

Product Type Single Medicine Product **Effective Date** 18/08/2021

Permitted Indications

Maintain/support female healthy hormonal balance

Maintain/support female reproductive system health

Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

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**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Passiflora incarnata herb top flowering Extract dry concentrate **25 mg**

Equivalent: Passiflora incarnata (Dry)

	500 mg
Vitex agnus-castus fruit Extract dry concentrate	**125 mg**
Equivalent: Vitex agnus-castus (Dry)	1.25 g

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

leucine

maltodextrin

microcrystalline cellulose