



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	373053	Estro Fortify
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	RN Labs Pty Ltd	
<b>Postal Address</b>	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
<b>ARTG Start Date</b>	18/08/2021	
<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'.

All products containing *Cimicifuga racemosa* must comply with the following condition of listing by carrying the label statement - Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

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 . Estro Fortify

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	18/08/2021
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#### Permitted Indications

Maintain/support female healthy hormonal balance  
Decrease/reduce/relieve symptoms of menopause  
Decrease/reduce/relieve hot flushes associated with menopause  
Maintain/support oestrogen hormone levels  
Maintain/support reproductive system health

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to infertility.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

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**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Actaea racemosa rhizome Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Actaea racemosa (Dry)	400 mg
<b>Asparagus racemosus root Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Asparagus racemosus (Dry)	600 mg
<b>Pinus radiata stem bark Extract dry concentrate</b>	<b>15 mg</b>
Equivalent: Pinus radiata (Dry)	1.5 g
<b>Trifolium pratense herb top flowering Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Trifolium pratense (Dry)	200 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
hypromellose  
leucine  
maltodextrin  
microcrystalline cellulose

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