

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373054	Progest Fortify
ARTG entry for	Medicine Listed	
Sponsor	RN Labs Pty Ltd	
Postal Address	18 / 93 Rivergate Australia	e Place, MURARRIE, QLD, 4172
ARTG Start Date	18/08/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	5
Conditions		

Conditions

Products

Visit www.tga.gov.au for contact information

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.

1 . Progest Fortify					
Product Type Si	ngle Medicine Product	Effective Date	18/08/2021		
Permitted Indications					
Maintain/support female healthy hormonal balance					
Maintain/support female re	eproductive system health				
Decrease/reduce/relieve symptoms of premenstrual tension					
Indication Requirements					
Label statement: If sympt	oms persist, talk to your health professional.				
Standard Indications					
No Standard Indications included on Record					
Specific Indications					
No Specific Indications inc	luded on Record				
Warnings					
No Warnings included on Record					
Additional Product information					
Pack Size/Poison inform	ation				
Pack Size		Poison Schedule			
Components					
1 . Formulation 1					
Dosage Form	Capsule, hard				
Route of Administration	n Oral				
Visual Identification					
Active Ingredients					
Passiflora incarnata he	erb top flowering Extract dry concentrate		25 mg		
Equivalent: Passiflora	incarnata (Dry)				
	Certificate document. ader to verify the current accuracy of the in	formation on the docu	Produced at 22.10.2021 at 04:07:11 AEDT ment subsequent to the date shown.		



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	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	

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leucine maltodextrin

microcrystalline cellulose

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This is not an ARTG Certificate document.