



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	168189	ENRICHED ANNA'S WILD YAM CREAM
ARTG entry for	Medicine Listed	
Sponsor	Anna's Farm Pty Ltd	
Postal Address	114 Jericho Road, MOORLAND, NSW, 2443 Australia	
ARTG Start Date	21/01/2010	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . ENRICHED ANNA'S WILD YAM CREAM

Product Type	Single Medicine Product	Effective Date	6/08/2010
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

Relief of menstrual symptoms. [Warning S required]

Specific Indications

A feminine harmonising cream traditionally used for the relief of menstrual discomfort and menopausal symptoms with their associated discomfort. For the relief of pre-menstrual breast pain.

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Contains ethanol. (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Cream
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Route of Administration Topical

Visual Identification

Active Ingredients

Aloe vera	50 microgram/g
d-alpha-tocopheryl acetate	20.0008 mg/g
Dioscorea villosa	200 mg/g
Equivalent: Dioscorea villosa	200 mg/g
Vitex agnus-castus	30 mg/g
Equivalent: Vitex agnus-castus	15 mg/g

Other Ingredients (Excipients)

Avocado oil
beta-tocopherol
carbomer U-10
cetostearyl alcohol
cetyl alcohol
delta-tocopherol
dimeticone 350
Fragrance (perfume)
gamma-tocopherol
glyceryl monostearate
isopropyl myristate
lecithin
PEG-20 stearate
propylene glycol
purified water
soy sterol
Soya Oil
trolamine
urea

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