



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333961	Femaren
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	10/04/2020	
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 . Femaren

Product Type	Single Medicine Product	Effective Date	3/11/2023
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Permitted Indications

Traditionally used in Chinese medicine to nourish/tonify/warm/boost/invigorate/strengthen kidney-essence/kidney-jing

Traditionally used in Chinese medicine to blood tonic/Enhance blood health

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause

Linked indication - Decrease/reduce/relieve mild rheumatic aches and pains

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menopause

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause

Linked indication - Decrease/reduce/relieve disturbed/restless sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause

Traditionally used in Western herbal medicine to decrease/reduce/relieve aggression/irritability associated with menopause

Traditionally used in Western herbal medicine to decrease/reduce/relieve moodiness/mood swings associated with menopause

Traditionally used in Western herbal medicine to maintain/support healthy reproductive hormones

Indication Requirements

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

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to hormone imbalances.

Product presentation must only refer to mild rheumatic aches/pains.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to kidney disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).
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

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Actaea racemosa rhizome Extract dry concentrate	100 mg
Equivalent: Actaea racemosa (Dry)	400 mg
Anemarrhena asphodeloides root and rhizome Extract dry concentrate	85 mg
Equivalent: Anemarrhena asphodeloides (Dry)	850 mg
Angelica polymorpha root Extract dry concentrate	50 mg
Equivalent: Angelica polymorpha (Dry)	750 mg
Asparagus racemosus root Extract dry concentrate	133.33 mg
Equivalent: Asparagus racemosus (Dry)	800 mg
Curculigo orchoides root Extract dry concentrate	71.43 mg
Equivalent: Curculigo orchoides (Dry)	500 mg
Epimedium sagittatum leaf Extract dry concentrate	43.33 mg
Equivalent: Epimedium sagittatum (Dry)	650 mg
Vitex agnus-castus fruit Extract dry concentrate	25 mg
Equivalent: Vitex agnus-castus (Dry)	250 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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