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'.

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.

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.

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 . Femaren

Product Type Single Medicine Product **Effective Date** 10/04/2020

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

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 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 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 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 kidney disease.

Product presentation must not imply or refer to hormone imbalances.

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.

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

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 orchioides root Extract dry concentrate	**71.43 mg**
Equivalent: Curculigo orchioides (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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