



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		294342	Femular
ARTG entry for	Medicine Listed		
Sponsor	SFI Australasia		
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia		
ARTG Start Date	26/09/2017		
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 . Femular

Product Type	Single Medicine Product	Effective Date	14/03/2024
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Relieve feelings of general malaise/general debility in post-menopausal women
Relieve feelings of general malaise/general debility in pre-menopausal women
Relieve feelings of general malaise/general debility in peri-menopausal women
Relieve weariness/tiredness/fatigue/feeling of weakness in post-menopausal women
Relieve weariness/tiredness/fatigue/feeling of weakness in pre-menopausal women
Relieve weariness/tiredness/fatigue/feeling of weakness in peri-menopausal women
Decrease/reduce/relieve excessive perspiration/sweating in peri-menopausal women
Decrease/reduce/relieve excessive perspiration/sweating in post-menopausal women
Decrease/reduce/relieve excessive perspiration/sweating in premenstrual woman
Decrease/reduce/relieve spontaneous sweating in peri-menopausal women
Decrease/reduce/relieve spontaneous sweating in pre-menopausal women
Decrease/reduce/relieve spontaneous sweating in post-menopausal women
Decrease/reduce/relieve mild joint aches and pains in post-menopausal women
Decrease/reduce/relieve mild joint aches and pains in peri-menopausal women
Decrease/reduce/relieve mild joint aches and pains in pre-menopausal women
Relieve irritability in peri-menopausal women
Relieve irritability in post-menopausal women
Relieve irritability in pre-menopausal women
Decrease/reduce/relieve symptoms of mild anxiety in peri-menopausal women
Decrease/reduce/relieve symptoms of mild anxiety in pre-menopausal women
Decrease/reduce/relieve symptoms of mild anxiety in post-menopausal women
Helps reduce occurrence of symptoms of mild anxiety in peri-menopausal women
Helps reduce occurrence of symptoms of mild anxiety in post-menopausal women
Helps reduce occurrence of symptoms of mild anxiety in pre-menopausal women
Decrease/reduce/relieve headache symptoms in peri-menopausal women
Decrease/reduce/relieve headache symptoms in post-menopausal women
Decrease/reduce/relieve headache symptoms in pre-menopausal women



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Helps reduce occurrence of symptoms of headaches in post-menopausal women
Helps reduce occurrence of symptoms of headaches in peri-menopausal women
Helps reduce occurrence of symptoms of headaches in pre-menopausal women
Maintain/support neuroendocrine function in post-menopausal women
Maintain/support neuroendocrine function in peri-menopausal women
Maintain/support neuroendocrine function in pre-menopausal women
Support healthy emotional/mood balance in post-menopausal women
Support healthy emotional/mood balance in pre-menopausal women
Support healthy emotional/mood balance in peri-menopausal women
Decrease/reduce/relieve sleeplessness in pre-menopausal women
Decrease/reduce/relieve sleeplessness in post-menopausal women
Decrease/reduce/relieve sleeplessness in peri-menopausal women
Maintain/support healthy female hormonal balance during menopause
Helps decrease/reduce/relieve night sweats associated with menopause
Decrease/reduce/relieve symptoms of menopause
Linked indication - Decrease/reduce/relieve spontaneous sweating
Linked indication - Decrease/reduce/relieve excessive perspiration/sweating
Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
Linked indication - Relieve feelings of general malaise/general debility
Linked indication - Decrease/reduce/relieve mild joint aches and pains
Linked indication - Decrease/reduce/relieve sleeplessness
Linked indication - Helps reduce occurrence of symptoms of mild anxiety
Linked indication - Helps reduce occurrence of symptoms of mild anxiety
Linked indication - Helps reduce occurrence of symptoms of headaches
Linked indication - Maintain/support neuroendocrine function
Linked indication - Support healthy emotional/mood balance
Linked indication - Relieve irritability
Helps reduce occurrence of menopausal symptoms
Decrease/reduce/relieve hot flushes associated with menopause
Decrease/reduce/relieve aggression/irritability associated with menopause
Decrease/reduce/relieve moodiness/mood swings associated with menopause

Indication Requirements

Product presentation must only refer to mild anxiety.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
Product presentation must only refer to mild joint symptoms.
Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains lactose (or words to that effect).
(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [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



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

Actaea racemosa root and rhizome Extract dry concentrate	8.7 mg
Equivalent: Actaea racemosa (Dry)	42.25 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
croscarmellose sodium
lactose monohydrate
magnesium stearate
microcrystalline cellulose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary