Public Summary

Summary for ARTG Entry:	232091 Femular Forte
ARTG entry for	Medicine Listed
Sponsor	SFI Australasia
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia
ARTG Start Date	22/12/2014
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.

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 . Femular Forte

Product Type Single Medicine Product **Effective Date** 18/10/2019

Permitted Indications

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

Relieve irritability in post-menopausal women

Decrease/reduce/relieve symptoms of mild anxiety in pre-menopausal women

Decrease/reduce/relieve symptoms of mild anxiety in post-menopausal women

Decrease/reduce/relieve 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

Helps reduce occurrence of symptoms of mild anxiety in peri-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

Helps reduce occurrence of symptoms of headaches in peri-menopausal women

Helps reduce occurrence of symptoms of headaches in post-menopausal women

Helps reduce occurrence of symptoms of headaches

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 pre-menopausal women

Support healthy emotional/mood balance in post-menopausal women

Support healthy emotional/mood balance in peri-menopausal women

Decrease/reduce/relieve sleeplessness in post-menopausal women

Decrease/reduce/relieve sleeplessness in peri-menopausal women

Decrease/reduce/relieve sleeplessness in pre-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 - Relieve feelings of general malaise/general debility
- Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Linked indication - Decrease/reduce/relieve excessive perspiration/sweating
- Linked indication - Decrease/reduce/relieve spontaneous sweating
- 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 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 not imply or refer to mental illnesses, disorders or conditions.

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

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must only refer to mild anxiety.

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains lactose (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.

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, uncoated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Actaea racemosa root and rhizome Extract dry concentrate	**17.35 mg**
Equivalent: Actaea racemosa (Dry)	84.5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
croscarmellose sodium
lactose monohydrate
magnesium stearate
microcrystalline cellulose