



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	110627	FEMME OESTROPLEX
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	30/09/2004	
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 . FEMME OESTROPLEX

Product Type	Single Medicine Product	Effective Date	26/08/2020
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Permitted Indications

- Helps decrease/reduce homocysteine levels
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of mild anxiety
- Decrease/reduce/relieve headache symptoms
- Decrease/reduce/relieve sleeplessness
- Maintain/support healthy female hormonal balance during menopause
- Decrease/reduce/relieve symptoms of menopause
- Decrease/reduce/relieve symptoms of menopause
 - Linked indication - Decrease/reduce/relieve sleeplessness
 - Linked indication - Decrease/reduce/relieve aggression/irritability associated with menopause
 - Linked indication - Decrease/reduce/relieve hot flushes associated with menopause
 - Linked indication - Helps decrease/reduce/relieve night sweats associated with menopause
- Decrease/reduce/relieve hot flushes associated with menopause

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (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.

St John's Wort affects the way many prescription medicines work, including the oral contraceptive pill. Consult your doctor.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

Actaea racemosa root and rhizome Extract dry concentrate	153.85 mg
Equivalent: Actaea racemosa (Dry)	1 g
calcium pantothenate	100 mg
Equivalent: pantothenic acid	91.7 mg
cyanocobalamin	.4 mg
d-alpha-tocopheryl acetate	103.401 mg
folic acid	400 microgram
Hypericum perforatum herb top Extract dry concentrate	209.302 mg
Equivalent: Hypericum perforatum (Dry)	900 mg
Pueraria lobata root Extract dry concentrate	111.12 mg
Equivalent: Pueraria lobata (Dry)	2 g
pyridoxal 5-phosphate	10 mg
Equivalent: pyridoxine	6.846 mg
pyridoxine hydrochloride	15 mg
Equivalent: pyridoxine	12.396 mg
Ziziphus jujuba fruit Extract dry concentrate	225 mg
Equivalent: Ziziphus jujuba (Dry)	900 mg

Other Ingredients (Excipients)

calcium silicate
carrageenan
croscarmellose sodium
Gelatin
hypromellose
macrogol 8000
magnesium stearate
mannitol
microcrystalline cellulose
silicon dioxide
stearic acid

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