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

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 hot flushes associated with menopause
- Linked indication - Helps decrease/reduce/relieve night sweats associated with menopause
- Linked indication - Decrease/reduce/relieve aggression/irritability 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 only refer to mild anxiety.

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

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.

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.

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, 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
hyprolose
macrogol 8000
magnesium stearate
mannitol
microcrystalline cellulose
silicon dioxide
stearic acid

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