



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	226160	METAGENICS FEMMEX
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	23/07/2014	
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'.

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 . METAGENICS FEMMEX

Product Type	Single Medicine Product	Effective Date	30/04/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support natural liver cleansing/detoxification processes
Maintain/support general health and wellbeing
Maintain/support healthy body tissues
Decrease/reduce/relieve muscle cramps
Helps decrease/reduce/relieve mild muscle spasms/twitches
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Support healthy stress response in the body
Traditionally used in Western herbal medicine to soothe/calm nerves
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Traditionally used in Western herbal medicine to soporific/induces sleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Maintain/support female reproductive system health
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve menstrual spasms/cramps
Decrease/reduce/relieve menstruation pain/dysmenorrhoea
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
Decrease/reduce/relieve symptoms of premenstrual tension
Maintain/support healthy female hormonal balance during menopause
Maintain/support oestrogen hormone levels
Maintain/support preconception health
Maintain/support reproductive system health



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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.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must only refer to detoxification in relation to natural body processes.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Boswellia serrata gum oleoresin Extract dry concentrate	16.67 mg/g
Equivalent: Boswellia serrata (Fresh)	166.7 mg/g
Brassica oleracea var. italica sprout Powder	83.33 mg/g
calcium ascorbate dihydrate	67.23 mg/g
Equivalent: ascorbic acid	55.55 mg/g
calcium hydrogen phosphate dihydrate	119.27 mg/g
Equivalent: calcium	27.78 mg/g
calcium pantothenate	5.56 mg/g
chromic chloride hexahydrate	57 microgram/g
Equivalent: chromium	11.12 microgram/g
cyanocobalamin	.0278 mg/g
folic acid	27.77 microgram/g
magnesium amino acid chelate	333.33 mg/g
Equivalent: magnesium	33.33 mg/g
Matricaria chamomilla flower Extract dry concentrate	27.78 mg/g
Equivalent: Matricaria chamomilla (Dry)	166.68 mg/g
potassium iodide	10.9 microgram/g
Equivalent: iodine	8.33 microgram/g
pyridoxine hydrochloride	2.78 mg/g
Equivalent: pyridoxine	2.29 mg/g



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tyrosine	44.44 mg/g
zinc amino acid chelate	2.78 mg/g
Equivalent: zinc	556 microgram/g

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Flavour
hypromellose
maltodextrin
polacrillin
potable water
silicon dioxide
Steviol glycosides
xanthan gum

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