Public Summary

Summary for ARTG Entry:	226204	METAGENICS O-LIFT
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	24/07/2014	
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.

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 . METAGENICS O-LIFT

Product Type Single Medicine Product **Effective Date** 20/11/2019

Permitted Indications

Traditionally used in Chinese medicine to nourish/tonify/replenish kidney-yin

Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating

Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function

Traditionally used in Chinese medicine to maintain/support healthy adrenal gland function

Traditionally used in Chinese medicine to help maintain/support emotional wellbeing

Traditionally used in Chinese medicine to decrease/reduce/relieve hot flushes associated with mild anxiety

Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Maintain/support healthy female hormonal balance during menopause

Traditionally used in Chinese medicine to helps decrease/reduce/relieve night sweats associated with menopause

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menopause

Maintain/support oestrogen hormone levels

Indication Requirements

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

Product presentation must not imply or refer to any adrenal related diseases.

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

Product presentation must not imply or refer to kidney disease.

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

Product presentation must only refer to mild anxiety.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.

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).

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

Alisma orientale	**92 mg**
Equivalent: Alisma orientale	920 mg
Anemarrhena asphodeloides	**89 mg**
Equivalent: Anemarrhena asphodeloides	890 mg
Cornus officinalis	**156 mg**
Equivalent: Cornus officinalis	1.56 g
Dioscorea oppositifolia	**156 mg**
Equivalent: Dioscorea oppositifolia	1.56 g
Paeonia suffruticosa	**92 mg**
Equivalent: Paeonia suffruticosa	920 mg
Rehmannia glutinosa	**320 mg**
Equivalent: Rehmannia glutinosa	3.2 g
Wolfiporia cocos	**92 mg**
Equivalent: Wolfiporia cocos	920 mg
Ziziphus jujuba var. spinosa	**111 mg**
Equivalent: Ziziphus jujuba var. spinosa	1.11 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
sodium starch glycollate type A

Public Summary

Public Summary