

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 377731 METAGENICS O-LIFT

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Nustralia

ARTG Start Date 10/11/2021

Product Category Medicine

Status Active

Approval Area Listed Medicines

Conditions

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.

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 10/11/2021

Permitted Indications

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

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

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

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

 $\label{thm:condition} \mbox{Traditionally used in Chinese medicine to maintain/support healthy adrenal gland function}$

Traditionally used in Western herbal 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

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

Product presentation must not imply or refer to kidney disease.

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 any adrenal related diseases.

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.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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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 rhizome Extract dry concentrate	92 mg
Equivalent: Alisma orientale (Dry)	920 mg
Anemarrhena asphodeloides rhizome Extract dry concentrate	89 mg
Equivalent: Anemarrhena asphodeloides (Dry)	890 mg
Cornus officinalis fruit Extract dry concentrate	156 mg
Equivalent: Cornus officinalis (Dry)	1.56 g
Dioscorea oppositifolia rhizome Extract dry concentrate	156 mg
Equivalent: Dioscorea oppositifolia (Dry)	1.56 g
Paeonia suffruticosa root bark Extract dry concentrate	92 mg
Equivalent: Paeonia suffruticosa (Dry)	920 mg
Rehmannia glutinosa root Extract dry concentrate	320 mg
Equivalent: Rehmannia glutinosa (Dry)	3.2 g
Wolfiporia cocos fruiting body Extract dry concentrate	92 mg
Equivalent: Wolfiporia cocos (Dry)	920 mg
Ziziphus jujuba var. spinosa seed Extract dry concentrate	111 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	1.11 g

Other Ingredients (Excipients)

colloidal anhydrous silica

croscarmellose sodium

glycerol

hypromellose

magnesium stearate

microcrystalline cellulose

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