



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	226231	METAGENICS P-LIFT
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	25/07/2014	
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 P-LIFT

Product Type	Single Medicine Product	Effective Date	19/03/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support healthy thyroid gland function
- Decrease/reduce/relieve symptoms of stress
- Maintain/support female healthy hormonal balance during the reproductive cycle
- Maintain/support female reproductive system health
- Decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Maintain/support/regulate healthy menstrual cycle
- Decrease/reduce/relieve menstrual spasms/cramps
- Decrease/reduce/relieve menstruation pain/dysmenorrhoea
- Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
- Decrease/reduce/relieve symptoms of premenstrual tension
- Decrease/reduce/relieve symptoms of premenstrual tension
 - Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
 - Linked indication - Temporarily relieve mild fluid retention
 - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
 - Linked indication - Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
 - Linked indication - Decrease/reduce headache duration
 - Linked indication - Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
 - Linked indication - Helps reduce occurrence of symptoms of headaches
- Maintain/support healthy reproductive hormones

Indication Requirements

- Product presentation must only refer to mild fluid retention.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to any thyroid related diseases.

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Product presentation must not imply or refer to hormone imbalances.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to cardiovascular or renal conditions.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Label statement: If fluid retention persists, seek medical advice (or words to that effect).
 Product presentation must not imply or refer to gastro oesophageal reflux disease.

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).
 If fluid retention persists, seek medical advice (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.
 Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).
 This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

lutein	5.0001 mg
mixed (low-alpha type) tocopherols concentrate	50.0016 mg
potassium iodide	196.21 microgram
Equivalent: iodine	150 microgram
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.14 mg
selenomethionine	250 microgram
Equivalent: selenium	100 microgram
Vitex agnus-castus fruit Extract dry concentrate	200 mg
Equivalent: Vitex agnus-castus (Dry)	2 g
Withania somnifera root Extract dry concentrate	180 mg
Equivalent: Withania somnifera (Dry)	4.5 g
zeaxanthin	.2857 mg
zinc amino acid chelate	125 mg
Equivalent: zinc	25 mg
Zingiber officinale rhizome Extract dry concentrate	62.5 mg
Equivalent: Zingiber officinale (Dry)	1 g

Other Ingredients (Excipients)

Acacia
ascorbyl palmitate
beta-tocopherol
calcium hydrogen phosphate dihydrate

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citric acid
colloidal anhydrous silica
croscarmellose sodium
crospovidone
delta-tocopherol
dl-alpha-tocopherol
gamma-tocopherol
hyplose
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
potable water
sodium ascorbate
stearic acid
sucrose
Sunflower Oil
tapioca starch

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