



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	226231	METAGENICS P-LIFT
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	25/07/2014	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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
  - 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 - Helps reduce occurrence of symptoms of headaches
  - Linked indication - Decrease/reduce headache duration
  - Linked indication - Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
  - Linked indication - Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
- Decrease/reduce/relieve symptoms of premenstrual tension
- Maintain/support healthy reproductive hormones

#### Indication Requirements

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



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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.

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

Product presentation must not imply or refer to hormone imbalances.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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.

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).

If fluid retention persists, seek medical advice (or words to that effect).

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

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

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