



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

## Public Summary

<b>Summary for ARTG Entry:</b>	217489	METAGENICS OVARIANNE
<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>	19/11/2013	
<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 OVARIANNE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/03/2020
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Traditionally used in Chinese medicine to body tonic  
Helps maintain/support transport of oxygen in the body  
Traditionally used in Chinese medicine to maintain/support female reproductive system health  
Traditionally used in Ayurvedic medicine to maintain/support female reproductive system health  
Maintain/support female reproductive system health  
Traditionally used in Chinese medicine to maintain/support/regulate healthy menstrual cycle  
Traditionally used in Chinese medicine to female tonic

#### Indication Requirements

Product presentation must not imply or refer to heart 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).  
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



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

Pack Size

Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Angelica polymorpha</b>	<b>180 mg</b>
Equivalent: Angelica polymorpha	1.8 g
<b>Asparagus racemosus</b>	<b>294.118 mg</b>
Equivalent: Asparagus racemosus	2.5 g
<b>Codonopsis pilosula</b>	<b>140.625 mg</b>
Equivalent: Codonopsis pilosula	1.125 g
<b>d-alpha-tocopheryl acid succinate</b>	<b>82.8 mg</b>
Equivalent: d-alpha-tocopherol	100 IU
<b>iron amino acid chelate</b>	<b>25 mg</b>
Equivalent: iron	5 mg
<b>Rehmannia glutinosa</b>	<b>150 mg</b>
Equivalent: Rehmannia glutinosa	1.5 g
<b>Zingiber officinale</b>	<b>12.5 mg</b>
Equivalent: Zingiber officinale	500 mg

**Other Ingredients (Excipients)**

**Carnauba Wax**  
**citric acid**  
**croscarmellose sodium**  
**ethylcellulose**  
**hypromellose**  
**macrogol 8000**  
**magnesium stearate**  
**maltodextrin**  
**microcrystalline cellulose**  
**silicon dioxide**  
**soy polysaccharide**  
**stearic acid**

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary