



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

## Public Summary

<b>Summary for ARTG Entry:</b>	197899	METAGENICS GYNO CLEAR
<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>	25/05/2012	
<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'.

This medicine contains a preparation of Carthamus tinctorius flower for oral use. From 1 July 2011 all Listed Medicines containing preparations of Carthamus tinctorius flower for oral use must include the label advisory statement 'Do not use if pregnant or likely to become pregnant'.

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 GYNO CLEAR

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/04/2020
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### Permitted Indications

Traditionally used in Chinese medicine to warm and invigorate blood circulation  
Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal pain/discomfort  
Traditionally used in Chinese medicine to improve menstrual flow  
Traditionally used in Japanese herbal medicine to maintain/support/regulate healthy menstrual cycle  
Traditionally used in Chinese medicine to maintain/support/regulate healthy menstrual cycle  
Traditionally used in Chinese medicine to decrease/reduce heavy menstruation/periods  
Traditionally used in Japanese herbal medicine to decrease/reduce heavy menstruation/periods  
Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea  
Traditionally used in Japanese herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea  
Traditionally used in Japanese herbal medicine to decrease/reduce/relieve symptoms of premenstrual tension  
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of premenstrual tension  
Traditionally used in Japanese herbal medicine to decrease/reduce/relieve symptoms of menstruation  
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menstruation

### Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

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

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 gastro oesophageal reflux disease.

### Standard Indications



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Therapeutic Goods Administration

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).

Do not use if pregnant or likely to become pregnant (or words to that effect)

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Carthamus tinctorius flower Extract dry concentrate</b>	<b>92 mg</b>
Equivalent: Carthamus tinctorius (Dry)	920 mg
<b>Cinnamomum cassia twig bark Extract dry concentrate</b>	<b>92 mg</b>
Equivalent: Cinnamomum cassia (Dry)	920 mg
<b>Paeonia lactiflora root Extract dry concentrate</b>	<b>92 mg</b>
Equivalent: Paeonia lactiflora (Dry)	920 mg
<b>Paeonia suffruticosa root bark Extract dry concentrate</b>	<b>92 mg</b>
Equivalent: Paeonia suffruticosa (Dry)	920 mg
<b>Salvia miltiorrhiza root and rhizome Extract dry concentrate</b>	<b>90 mg</b>
Equivalent: Salvia miltiorrhiza (Dry)	900 mg
<b>Wolfiporia cocos fruiting body Extract dry concentrate</b>	<b>92 mg</b>
Equivalent: Wolfiporia cocos (Dry)	920 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
disodium edetate  
gellan gum  
hypromellose  
magnesium stearate  
potable water  
potassium acetate

Public Summary

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