



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

## Public Summary

<b>Summary for ARTG Entry:</b>	201646	METAGENICS MENSTROCARE
<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>	6/10/2012	
<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'.

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 MENSTROCARE

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/03/2020
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### Permitted Indications

Maintain/support female healthy hormonal balance during the reproductive cycle  
Maintain/support female reproductive system health  
Decrease/reduce/relieve menstrual cycle irregularity/irregular periods  
Traditionally used in Chinese medicine to 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  
Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea  
Decrease/reduce/relieve symptoms of premenstrual tension  
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

### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to cardiovascular or renal conditions.  
Product presentation must not imply or refer to gastro oesophageal reflux disease.  
Label statement: If fluid retention persists, seek medical advice (or words to that effect).  
Product presentation must only refer to mild fluid retention.

### Standard Indications

No Standard Indications included on Record



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**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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).

**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>Angelica polymorpha</b>	<b>70 mg</b>
Equivalent: Angelica polymorpha	700 mg
<b>Cinnamomum cassia</b>	<b>55 mg</b>
Equivalent: coumarin	.11 microgram
Equivalent: Cinnamomum cassia	550 mg
<b>Epimedium sagittatum</b>	<b>55 mg</b>
Equivalent: Epimedium sagittatum	550 mg
<b>Glycyrrhiza uralensis</b>	<b>55 mg</b>
Equivalent: Glycyrrhiza uralensis	550 mg
<b>Ligusticum striatum</b>	<b>55 mg</b>
Equivalent: Ligusticum striatum	550 mg
<b>Paeonia lactiflora</b>	<b>55 mg</b>
Equivalent: Paeonia lactiflora	550 mg
<b>pyridoxine hydrochloride</b>	<b>10 mg</b>
Equivalent: pyridoxine	8.23 mg
<b>riboflavin</b>	<b>5 mg</b>
<b>Tetradium ruticarpum</b>	<b>70 mg</b>
Equivalent: Tetradium ruticarpum	700 mg
Equivalent: oxedrine	210 microgram
<b>Vitex agnus-castus</b>	<b>70 mg</b>
Equivalent: Vitex agnus-castus	700 mg
<b>Zingiber officinale</b>	<b>55 mg</b>
Equivalent: Zingiber officinale	550 mg

**Other Ingredients (Excipients)**

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

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