



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	201646	METAGENICS MENSTROCARE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	6/10/2012	
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 MENSTROCARE

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

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

Angelica polymorpha root Extract dry concentrate	70 mg
Equivalent: Angelica polymorpha (Dry)	700 mg
Cinnamomum cassia twig bark Extract dry concentrate	55 mg
Equivalent: Cinnamomum cassia (Dry)	550 mg
Epimedium sagittatum herb Extract dry concentrate	55 mg
Equivalent: Epimedium sagittatum (Dry)	550 mg
Glycyrrhiza uralensis root and rhizome Extract dry concentrate	55 mg
Equivalent: Glycyrrhiza uralensis (Dry)	550 mg
Ligusticum striatum rhizome Extract dry concentrate	55 mg
Equivalent: Ligusticum striatum (Dry)	550 mg
Paeonia lactiflora root Extract dry concentrate	55 mg
Equivalent: Paeonia lactiflora (Dry)	550 mg
pyridoxine hydrochloride	10 mg
Equivalent: pyridoxine	8.23 mg
riboflavin	5 mg
Tetradium ruticarpum fruit Extract dry concentrate	70 mg
Equivalent: Tetradium ruticarpum (Dry)	700 mg
Vitex agnus-castus fruit Extract dry concentrate	70 mg
Equivalent: Vitex agnus-castus (Dry)	700 mg
Zingiber officinale rhizome Extract dry concentrate	55 mg
Equivalent: Zingiber officinale (Fresh)	550 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

potable water

potassium acetate

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