



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	326824	Hormone + PMS Support
ARTG entry for	Medicine Listed	
Sponsor	JSHealth Vitamins Pty Ltd	
Postal Address	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
ARTG Start Date	28/11/2019	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Hormone + PMS Support

Product Type	Effective Date
Single Medicine Product	28/11/2019

Permitted Indications

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood

Maintain/support energy production

Helps maintain/support healthy blood sugar/glucose

Maintain/support muscle function

Maintain/support muscle relaxation

Maintain/support nervous system health

Maintain/support nervous system function

Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods

Traditionally used in Western herbal medicine to 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 serious cardiovascular conditions.

Product presentation must not imply or refer to hormone imbalances.

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

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.



Australian Government
Department of Health
 Therapeutic Goods Administration

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Angelica polymorpha root Extract dry concentrate	250 mg
Equivalent: Angelica polymorpha (Dry)	2.5 g
Asparagus racemosus	50 mg
Brassica oleracea var. italica flower Extract dry concentrate	20 mg
Equivalent: Brassica oleracea var. italica (Dry)	200 mg
Corydalis ambigua rhizome Extract dry concentrate	30 mg
Equivalent: Corydalis ambigua (Dry)	300 mg
Curcuma longa rhizome Extract dry concentrate	10 mg
Equivalent: Curcuma longa (Dry)	100 mg
magnesium citrate	308.642 mg
Equivalent: magnesium	47.685 mg
nicotinamide	15 mg
Paeonia lactiflora root Extract dry concentrate	71.429 mg
Equivalent: Paeonia lactiflora (Dry)	500 mg
pyridoxine hydrochloride	10 mg
Equivalent: pyridoxine	8.227 mg
Viburnum opulus twig bark Extract dry concentrate	30 mg
Equivalent: Viburnum opulus (Dry)	300 mg
Vitex agnus-castus fruit Extract dry concentrate	50 mg
Equivalent: Vitex agnus-castus (Dry)	500 mg
Withania somnifera root Extract dry concentrate	20 mg
Equivalent: Withania somnifera (Dry)	250 mg
Zingiber officinale root Extract dry concentrate	22.75 mg
Equivalent: Zingiber officinale (Dry)	250 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- hypromellose
- macrogol 400

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
purified water
silicon dioxide

© 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