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	Single Medicine Product	**Effective Date**	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

Product presentation must not imply or refer to hormone imbalances.

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.

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.

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

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
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
purified water
silicon dioxide

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