



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	394107	In-Flow Period & PMS Relief
ARTG entry for	Medicine Listed	
Sponsor	ashaya Pty Ltd	
Postal Address	7 Jacqueline Close, Bayview, NSW, 2104 Australia	
ARTG Start Date	19/08/2022	
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.

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 . In-Flow Period & PMS Relief

Product Type	Single Medicine Product	Effective Date	14/11/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to balance Kapha
- Traditionally used in Ayurvedic medicine to balance Pitta
- Traditionally used in Ayurvedic medicine to balance Vata
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Maintain/support energy production
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support eye health
- Traditionally used in Ayurvedic medicine to temporarily relieve mild fluid retention
- Traditionally used in Ayurvedic medicine to rejuvenating tonic
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Anti-inflammatory/relieve inflammation
- Maintain/support bone mass/density/integrity
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal cramping
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Ayurvedic medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Ayurvedic medicine to digestive tonic/Improve digestive weakness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stomach upsets
- Maintain/support immune system to fight illness

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Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
Helps reduce occurrence of muscle cramp
Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
Traditionally used in Ayurvedic medicine to support healthy stress response in the body
Traditionally used in Western herbal medicine to relieve irritability
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support memory/mental recall
Maintain/support brain function
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve symptoms of mild tension headache
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Maintain/support nervous system function
Traditionally used in Western herbal medicine to support healthy emotional/mood balance
Support healthy emotional/mood balance
Maintains/supports refreshing sleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Maintain/support female healthy hormonal balance
Traditionally used in Ayurvedic medicine to maintain/support female reproductive system health
Decrease/reduce/relieve menstruation pain/dysmenorrhoea
Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
Decrease/reduce/relieve symptoms of premenstrual tension
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of premenstrual tension
Traditionally used in Ayurvedic medicine to maintain/support breast milk production/lactation
Traditionally used in Ayurvedic medicine to helps enhance/promote preconception health
Traditionally used in Ayurvedic medicine to female tonic
Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido
Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
Maintain/support skin health
Traditionally used in Ayurvedic medicine to helps decrease/reduce/relieve symptoms of medically diagnosed cystitis
Traditionally used in Ayurvedic medicine to aid/assist flushing of the urinary tract
Traditionally used in Ayurvedic medicine to enhance/promote/increase urine output

Indication Requirements

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

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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

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

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must only refer to mild anxiety.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

Product presentation must only refer to medically diagnosed cystitis.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Label statement: If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Product presentation must only refer to mild fluid retention.

Product presentation must not imply or refer to infertility.



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If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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.

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

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to kidney disease.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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

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

If pain or irritation persists for more than 48 hours, consult your doctor. The presence of blood in the urine warrants immediate medical attention (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

Asparagus racemosus root Extract dry concentrate	41.67 mg/g
Equivalent: Asparagus racemosus (Dry)	250 mg/g
Crocus sativus stigma Extract dry concentrate	7 mg/g
Equivalent: Crocus sativus (Dry)	21 mg/g
Curcuma longa rhizome Extract dry concentrate standardised	15.38 mg/g
Equivalent: Curcuma longa (Powder)	999.7 mg/g
magnesium glycinate dihydrate	219.3 mg/g
Equivalent: magnesium	25 mg/g
Matricaria chamomilla flower Extract dry concentrate	83.33 mg/g
Equivalent: Matricaria chamomilla (Dry)	500 mg/g
Melissa officinalis leaf Extract dry concentrate	75 mg/g
Equivalent: Melissa officinalis (Dry)	750 mg/g
Piper nigrum fruit Extract dry concentrate	5 mg/g
Equivalent: Piper nigrum (Dry)	102.5 mg/g
potassium iodide	4.9 microgram/g
Equivalent: iodine	3.75 microgram/g
pyridoxine hydrochloride	4.862 mg/g
Equivalent: pyridoxine	4 mg/g
Withania somnifera root Extract dry concentrate	60 mg/g

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Equivalent: Withania somnifera (Dry)	750 mg/g
zinc glycinate	4.08 mg/g
Equivalent: zinc	1.25 mg/g

Other Ingredients (Excipients)

- Beta vulgaris
- citric acid
- colloidal anhydrous silica
- Flavour
- glycine
- maltodextrin
- Stevia rebaudiana

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