



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	400193	Re-Glow Perimenopause Relief
ARTG entry for	Medicine Listed	
Sponsor	ashaya Pty Ltd	
Postal Address	7 Jacqueline Close, Bayview, NSW, 2104 Australia	
ARTG Start Date	27/11/2022	
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 . Re-Glow Perimenopause Relief

Product Type	Single Medicine Product	Effective Date	27/11/2022
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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
- Traditionally used in Chinese 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
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support eye health
- Helps maintain/support eye macula health
- Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
- Decrease/reduce/relieve spontaneous sweating in peri-menopausal women
- Traditionally used in Chinese medicine to longevity tonic
- 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 mild joint aches and pains
- 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 symptoms of indigestion/dyspepsia
- Traditionally used in Ayurvedic medicine to relieve digestive discomfort

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Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to digestive tonic/Improve digestive weakness
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
Traditionally used in Chinese medicine to maintain/support healthy immune system function
Maintain/support immune system to fight illness
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 decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support brain function
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Maintain/support nervous system function
Support healthy emotional/mood balance
Traditionally used in Western herbal medicine to soporific/induces sleep
Maintains/supports refreshing sleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep
Maintain/support female healthy hormonal balance in peri-menopausal women
Maintain/support female healthy hormonal balance
Maintain/support healthy female hormonal balance during menopause
Helps decrease/reduce/relieve night sweats associated with menopause
Traditionally used in Chinese medicine to helps decrease/reduce/relieve night sweats associated with menopause
Decrease/reduce/relieve symptoms of menopause
Decrease/reduce/relieve hot flushes associated with menopause
Decrease/reduce/relieve vaginal discomfort in peri-menopausal women
Decrease/reduce/relieve vaginal discomfort in post-menopausal women
Decrease/reduce/relieve vaginal dryness in peri-menopausal women
Decrease/reduce/relieve vaginal dryness in post-menopausal women
Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido
Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function
Maintain/support skin health
Traditionally used in Chinese medicine to kidney Tonic

Indication Requirements

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

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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 vision correction, faults or serious eye disease e.g. macular degeneration.

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.

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

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

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 not imply or refer to kidney disease.

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.



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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 only refer to mild joint symptoms.

Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (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.

Warning: In very rare cases, black cohosh has been associated with liver failure. If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

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

Actaea racemosa rhizome Extract dry concentrate	12.5 mg/g
Equivalent: Actaea racemosa (Dry)	50 mg/g
Astragalus membranaceus root Extract dry concentrate	50 mg/g
Equivalent: Astragalus membranaceus (Dry)	500 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
Humulus lupulus fruit Extract dry concentrate	50 mg/g
Equivalent: Humulus lupulus (Dry)	375 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
Piper nigrum fruit Extract dry concentrate	5 mg/g
Equivalent: Piper nigrum (Dry)	102.5 mg/g
Withania somnifera root Extract dry concentrate	60 mg/g
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

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glycine

maltodextrin

Stevia rebaudiana

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