



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	405182	Balance Hormone Support
ARTG entry for	Medicine Listed	
Sponsor	Whole Health Studio	
Postal Address	4 Glenelg Avenue, Mermaid Beach, QLD, 4218 Australia	
ARTG Start Date	21/02/2023	
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 . Balance Hormone Support

Product Type	Single Medicine Product	Effective Date	14/03/2023
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body when dietary intake is inadequate
- Maintain/support collagen formation when dietary intake is inadequate
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to kapha & Vata roga/relieve Kapaha & Vata disturbance
- Traditionally used in Ayurvedic medicine to balya/improve body strength
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to balance aggravated Vata
- Maintain/support energy levels when dietary intake is inadequate
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Maintain/support body metabolism/metabolic rate when dietary intake is inadequate
- Maintain/support energy production when dietary intake is inadequate
- Maintain/support heat/energy production/thermogenesis when dietary intake is inadequate
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing when dietary intake is inadequate
- Traditionally used in Ayurvedic medicine to anti-inflammatory/relieve inflammation
- Maintain/support connective tissue health when dietary intake is inadequate
- Aid/assist/helps connective tissue production/formation when dietary intake is inadequate
- Aid/assist healthy red blood cell production when dietary intake is inadequate
- Helps maintain/support haemoglobin formation/synthesis when dietary intake is inadequate
- Maintain/support blood capillary health when dietary intake is inadequate
- Maintain/support blood vessel health when dietary intake is inadequate
- Maintain/support healthy thyroid gland function when dietary intake is inadequate
- Maintain/support healthy thyroid hormones when dietary intake is inadequate
- Maintain/support thyroid gland health when dietary intake is inadequate
- Aid/assist thyroid hormone production when dietary intake is inadequate

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Maintain/support immune system health when dietary intake is inadequate
Maintain/support healthy immune system function when dietary intake is inadequate
Aid/assist/helps glucose/sugar/carbohydrate metabolism when dietary intake is inadequate
Aid/assist/helps protein synthesis in the body when dietary intake is inadequate
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) when dietary intake is inadequate
Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) when dietary intake is inadequate
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) when dietary intake is inadequate
Maintain/support (state vitamin/mineral) within normal range when dietary intake is inadequate
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Traditionally used in Ayurvedic medicine to support healthy body stress recovery
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
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Ayurvedic medicine to nerve tonic
Maintain/support nerve conduction when dietary intake is inadequate
Aid/assist/helps synthesis of neurotransmitters when dietary intake is inadequate
Maintain/support nervous system health when dietary intake is inadequate
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Traditionally used in Ayurvedic medicine to nervine/support nervous system
Maintain/support nervous system function when dietary intake is inadequate
Traditionally used in Ayurvedic medicine to soporific/induces 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
Maintain/support female healthy hormonal balance
Maintain/support female reproductive system health when dietary intake is inadequate
Maintain/support female reproductive system health
Traditionally used in Western herbal medicine to haemagogue/emmenagogue/promotes menstrual flow
Maintain/support/regulate healthy menstrual cycle
Maintain/support/regulate healthy menstrual cycle when dietary intake is inadequate
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of premenstrual tension
Maintain/support preconception health when dietary intake is inadequate in healthy females
Maintain/support healthy reproductive hormones when dietary intake is inadequate
Maintain/support healthy reproductive hormones in females
Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido
Maintain/support skin health when dietary intake is inadequate
Maintain/support skin integrity/structure when dietary intake is inadequate
Maintain/support skin regeneration when dietary intake is inadequate
Maintain/support wound healing when dietary intake is inadequate

Indication Requirements

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

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.

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 circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to any thyroid related diseases.

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).

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

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to abortifacient action.



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Product presentation must only refer to mild anxiety.

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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

If product is indicated for supplementation, 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 hormone imbalances.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].

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

ascorbic acid	25 mg
chromium picolinate	201 microgram
Equivalent: chromium	24 microgram
Cinnamomum verum stem bark Extract dry concentrate	3.34 mg
Equivalent: Cinnamomum verum (Dry)	33.4 mg
magnesium citrate	51.5 mg
Equivalent: magnesium	7.725 mg
Paeonia lactiflora root Extract dry concentrate	100 mg
Equivalent: Paeonia lactiflora (Dry)	1 g
Passiflora incarnata flower Extract dry concentrate	60 mg
Equivalent: Passiflora incarnata (Dry)	600 mg
potassium iodide	98.5 microgram
Equivalent: iodine	75 microgram
pyridoxine hydrochloride	6.08 mg
Equivalent: pyridoxine	5 mg
Silybum marianum fruit Extract dry concentrate	21.43 mg
Equivalent: Silybum marianum (Dry)	1.5 g
Vitex agnus-castus fruit Extract dry concentrate	75 mg
Equivalent: Vitex agnus-castus (Dry)	750 mg
Withania somnifera root Extract dry concentrate	150 mg
Equivalent: Withania somnifera (Dry)	1.5 g
zinc citrate dihydrate	12.78 mg
Equivalent: zinc	4 mg
Zingiber officinale rhizome Extract dry concentrate	3.03 mg

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Equivalent: Zingiber officinale (Dry)

33.33 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

maltodextrin

purified water

silicon dioxide

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