



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	385057	Menopause +
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
<b>ARTG Start Date</b>	3/03/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Menopause +**

Product Type	Single Medicine Product	Effective Date	3/03/2022
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Maintain/support energy production
- Traditionally used in Western herbal medicine to sudorific/diaphoretic/enhance/promote sweating/perspiration
- Traditionally used in Western herbal medicine to decrease/reduce/relieve excessive perspiration/sweating
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support bone health
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to antispasmodic/spasmodic
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Maintain/support nervous system health
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant
- Traditionally used in Western herbal medicine to nervine/support nervous system
- Maintain/support nervous system function
- Traditionally used in Western herbal medicine to haemagogue/emmenagogue/promotes menstrual flow
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of premenstrual tension
- Traditionally used in Western herbal medicine to helps reduce occurrence of premenstrual tension symptoms
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve night sweats associated with menopause
- Maintain/support skin health

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**Indication Requirements**

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 mental illnesses, disorders or conditions.

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

Product presentation must not imply or refer to abortifacient action.

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

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.

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 serious musculoskeletal or neurological conditions.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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.

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

**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**

<b>Actaea racemosa root and rhizome Extract dry concentrate</b>	<b>20 mg</b>
Equivalent: Actaea racemosa (Dry)	200 mg
<b>ascorbic acid</b>	<b>50 mg</b>
<b>Asparagus racemosus root Extract dry concentrate</b>	<b>10 mg</b>
Equivalent: Asparagus racemosus (Dry)	200 mg
<b>Brassica oleracea var. italica flower Extract dry concentrate</b>	<b>10 mg</b>
Equivalent: Brassica oleracea var. italica (Dry)	100 mg
<b>colecalfiferol</b>	<b>.0025 mg</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>20.66 mg</b>
<b>menaquinone 7</b>	<b>90 microgram</b>
<b>Passiflora incarnata flower Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Passiflora incarnata (Dry)	300 mg
<b>pyridoxal 5-phosphate</b>	<b>3.91 mg</b>
Equivalent: pyridoxine	2.5 mg
<b>Rehmannia glutinosa root Extract dry concentrate</b>	<b>20 mg</b>
Equivalent: Rehmannia glutinosa (Dry)	200 mg
<b>Salvia officinalis leaf Extract dry concentrate</b>	<b>167 mg</b>
Equivalent: Salvia officinalis (Dry)	1.169 g



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<b>Trifolium pratense herb Extract dry concentrate</b>	<b>250 mg</b>
Equivalent: Trifolium pratense (Dry)	1 g
<b>Vitex agnus-castus fruit Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Vitex agnus-castus (Dry)	250 mg
<b>Ziziphus jujuba seed Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: Ziziphus jujuba (Dry)	3 g

**Other Ingredients (Excipients)**

Acacia  
calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
d-alpha-tocopherol  
fractionated coconut oil  
hypromellose  
liquid glucose  
macrogol 400  
magnesium stearate  
maltodextrin  
medium chain triglycerides  
microcrystalline cellulose  
Peppermint Oil  
povidone  
silicon dioxide  
sodium ascorbate

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