



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	363513	Menopause Relief
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	28/04/2021	
<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 Relief

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/04/2021
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#### Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic in females
- Traditionally used in Western herbal medicine to decrease/reduce/relieve excessive perspiration/sweating
- Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of menopause
- Decrease/reduce/relieve symptoms of menopause
- Decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve hot flushes associated with menopause

#### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- 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.
- 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 mental illnesses, disorders or 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).

#### Additional Product information



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**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>Asparagus racemosus root Extract dry concentrate</b>	<b>88.235 mg</b>
Equivalent: Asparagus racemosus (Dry)	1.5 g
<b>Salvia officinalis leaf Extract dry concentrate</b>	<b>300 mg</b>
Equivalent: Salvia officinalis (Dry)	1.5 g
<b>Vitex agnus-castus fruit Extract dry concentrate</b>	<b>25 mg</b>
Equivalent: Vitex agnus-castus (Dry)	250 mg
<b>Ziziphus jujuba var. spinosa seed Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Ziziphus jujuba var. spinosa (Dry)	1.5 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
croscarmellose sodium  
hypromellose  
macrogol 400  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
povidone  
sodium starch glycollate

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