



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	293665	Menopause Relief
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	8/09/2017	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

Product Type	Single Medicine Product	Effective Date	22/04/2020
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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
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause
- 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.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

If symptoms persist, seek the advice of a healthcare professional.

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

If symptoms persist consult your healthcare practitioner (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

Asparagus racemosus root Extract dry concentrate	88.235 mg
Equivalent: Asparagus racemosus (Dry)	1.5 g
Salvia officinalis leaf Extract dry concentrate	300 mg
Equivalent: Salvia officinalis (Dry)	1.5 g
Vitex agnus-castus fruit Extract dry concentrate	25 mg
Equivalent: Vitex agnus-castus (Dry)	250 mg
Ziziphus jujuba var. spinosa seed Extract dry concentrate	150 mg
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
microcrystalline cellulose
povidone
sodium starch glycollate

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