



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	228734	Harmony Menopause
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	1/10/2014	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Harmony Menopause

Product Type	Single Medicine Product	Effective Date	22/01/2020
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Permitted Indications

- Traditionally used in Chinese medicine to clear/disperse/expel/dissipate/cool blood-heat
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Chinese medicine to helps decrease/reduce/relieve night sweats associated with menopause
- Traditionally used in European herbal medicine to decrease/reduce/relieve symptoms of menopause
 - Linked indication - Decrease/reduce/relieve mild joint aches and pains
 - Linked indication - Decrease/reduce/relieve muscle pain/ache/soreness
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menopause
 - Linked indication - Decrease/reduce/relieve excessive perspiration/sweating
 - Linked indication - Decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
 - Linked indication - Decrease/reduce/relieve aggression/irritability associated with menopause
- Traditionally used in Chinese medicine to decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Chinese medicine to decrease/reduce/relieve aggression/irritability associated with menopause

Indication Requirements

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
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

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you.

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

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 only refer to mild anxiety.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

Product presentation must only refer to mild joint symptoms.

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.

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 can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

Angelica polymorpha root Extract dry concentrate	50 mg
Equivalent: Angelica polymorpha (Dry)	200 mg
Bupleurum falcatum root Extract dry concentrate	20 mg
Equivalent: Bupleurum falcatum (Dry)	200 mg
calcium amino acid chelate	50 mg
Equivalent: calcium	10 mg
calcium hydrogen phosphate dihydrate	350 mg
Equivalent: phosphorus	63 mg
Equivalent: calcium	81.6 mg
colecalfiferol	.0025 mg
Dioscorea oppositifolia root and rhizome Extract dry concentrate	40 mg
Equivalent: Dioscorea oppositifolia (Dry)	200 mg
magnesium amino acid chelate	50 mg
Equivalent: magnesium	10 mg
Paeonia lactiflora root Extract dry concentrate	28.57 mg
Equivalent: Paeonia lactiflora (Dry)	200 mg
Rehmannia glutinosa root Extract dry concentrate	200 mg
Equivalent: Rehmannia glutinosa (Dry)	1.2 g
Vitex agnus-castus fruit Extract dry concentrate	10 mg
Equivalent: Vitex agnus-castus (Dry)	100 mg

Other Ingredients (Excipients)

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Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
dl-alpha-tocopherol
hydrogenated soya oil
hydrolysed gelatin
hypromellose
iron oxide red
macrogol 400
magnesium stearate
maize starch
maltodextrin
microcrystalline cellulose
silicon dioxide
sucrose

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