



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	295969	Harmony Menopause Day & Night
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	7/11/2017	
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.

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 Day & Night

Product Type	Composite Pack	Effective Date	22/01/2020
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Permitted Indications

- Traditionally used in Chinese medicine to clear/disperse/expel/dissipate/cool blood-heat
- 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 enhance/promote/increase refreshing sleep
- Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Chinese medicine to enhance/improve/promote/increase sleep quality/deep sleep
- Traditionally used in Chinese medicine to help decrease/reduce/relieve night sweats associated with menopause
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of menopause
 - Linked indication - Decrease/reduce/relieve excessive perspiration/sweating
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
 - Linked indication - Decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause
- Traditionally used in Chinese medicine to decrease/reduce/relieve hot flushes associated with menopause
- Traditionally used in Western herbal medicine to decrease/reduce/relieve aggression/irritability associated with menopause
- Traditionally used in Chinese medicine to decrease/reduce/relieve aggression/irritability associated with menopause

Indication Requirements

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

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

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

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

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 anxiety.

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
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Rehmannia glutinosa root Extract dry concentrate	633.33 mg
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Equivalent: Rehmannia glutinosa (Dry)	7.6 g
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Ziziphus jujuba var. spinosa seed Extract dry concentrate	200 mg
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Equivalent: Ziziphus jujuba var. spinosa (Dry)	10 g
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Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

iron oxide black

iron oxide red

iron oxide yellow

macrogol 3350

magnesium stearate

microcrystalline cellulose

polyvinyl alcohol

purified talc

titanium dioxide

2 . Formulation 2

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Angelica polymorpha root Extract dry concentrate	50 mg
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Public Summary



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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	350 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)

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
microcrystalline cellulose
silicon dioxide
sucrose

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Public Summary