



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

**Public Summary**

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

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**

<b>Product Type</b>	Composite Pack	<b>Effective Date</b>	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 Western herbal medicine to decrease/reduce/relieve symptoms of menopause
  - Linked indication - Decrease/reduce/relieve hot flushes 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
- 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**

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



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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.

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

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**

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

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**

<b>Rehmannia glutinosa root Extract dry concentrate</b>	<b>633.33 mg</b>
Equivalent: Rehmannia glutinosa (Dry)	7.6 g
<b>Ziziphus jujuba var. spinosa seed Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Ziziphus jujuba var. spinosa (Dry)	10 g

**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**

<b>Angelica polymorpha root Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Angelica polymorpha (Dry)	

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	200 mg
<b>Bupleurum falcatum root Extract dry concentrate</b>	<b>20 mg</b>
Equivalent: Bupleurum falcatum (Dry)	200 mg
<b>calcium amino acid chelate</b>	<b>50 mg</b>
Equivalent: calcium	10 mg
<b>calcium hydrogen phosphate</b>	<b>350 mg</b>
Equivalent: calcium	81.6 mg
<b>colecalfiferol</b>	<b>.0025 mg</b>
<b>Dioscorea oppositifolia root and rhizome Extract dry concentrate</b>	<b>40 mg</b>
Equivalent: Dioscorea oppositifolia (Dry)	200 mg
<b>magnesium amino acid chelate</b>	<b>50 mg</b>
Equivalent: magnesium	10 mg
<b>Paeonia lactiflora root Extract dry concentrate</b>	<b>28.57 mg</b>
Equivalent: Paeonia lactiflora (Dry)	200 mg
<b>Rehmannia glutinosa root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Rehmannia glutinosa (Dry)	1.2 g
<b>Vitex agnus-castus fruit Extract dry concentrate</b>	<b>10 mg</b>
Equivalent: Vitex agnus-castus (Dry)	100 mg
<b>Other Ingredients (Excipients)</b>	
<b>Carnauba Wax</b>	
<b>colloidal anhydrous silica</b>	
<b>croscarmellose sodium</b>	
<b>dl-alpha-tocopherol</b>	
<b>hydrogenated soya oil</b>	
<b>hydrolysed gelatin</b>	
<b>hypromellose</b>	
<b>iron oxide red</b>	
<b>macrogol 400</b>	
<b>magnesium stearate</b>	
<b>maize starch</b>	
<b>microcrystalline cellulose</b>	
<b>silicon dioxide</b>	
<b>sucrose</b>	

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