



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	229922	HARMONY BALANCE
<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>	29/10/2014	
<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 BALANCE**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/01/2020
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**Permitted Indications**

- Traditionally used in Chinese medicine to maintain/support nail health/strength/thickness
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps reduce occurrence of abdominal bloating
- Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal cramping
- Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal pain/discomfort
- Decrease/reduce/relieve abdominal pain/discomfort
- Traditionally used in Chinese medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Decrease/reduce/relieve headache symptoms
- Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
- Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms
- Decrease/reduce/relieve menstrual cycle irregularity/irregular periods
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
- Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
- Traditionally used in Western herbal medicine to decrease/reduce feelings of aggression/irritability associated with premenstrual tension
- Traditionally used in Chinese medicine to decrease/reduce feelings of aggression/irritability associated with premenstrual tension
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
- Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
- Traditionally used in Chinese medicine to decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
- Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension

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Traditionally used in Chinese medicine to decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension  
 Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of premenstrual tension  
 Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of premenstrual tension  
 Decrease/reduce/relieve symptoms of premenstrual tension  
 Traditionally used in Chinese medicine to maintain/support skin health

**Indication Requirements**

Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to gastro oesophageal reflux disease.  
 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 mental illnesses, disorders or conditions.  
 Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.  
 [Contains vitamin B6].

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Angelica polymorpha root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Angelica polymorpha (Dry)	2 g
<b>Bupleurum falcatum root Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Bupleurum falcatum (Dry)	1 g
<b>colecalfiferol</b>	<b>.0037 mg</b>
<b>Paeonia lactiflora root Extract dry concentrate</b>	<b>285.72 mg</b>
Equivalent: Paeonia lactiflora (Dry)	2 g
<b>pyridoxine hydrochloride</b>	<b>30.38 mg</b>
Equivalent: pyridoxine	25 mg
<b>Vitex agnus-castus fruit Extract dry concentrate</b>	<b>17.5 mg</b>
Equivalent: Vitex agnus-castus (Dry)	175 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
 Carnuba Wax  
 chlorophyllin-copper complex  
 colloidal anhydrous silica  
 croscarmellose sodium  
 dl-alpha-tocopherol  
 hydrogenated soya oil  
 hydrolysed gelatin

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hypromellose  
macrogol 400  
magnesium stearate  
maize starch  
microcrystalline cellulose  
silicon dioxide  
sucrose

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