



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	229922	HARMONY BALANCE
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	29/10/2014	
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 BALANCE

Product Type	Single Medicine Product	Effective Date	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



Australian Government
Department of Health
Therapeutic Goods Administration

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.

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).

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.

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

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

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba 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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