



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	222601	Harmony Restore
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	16/04/2014	
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.

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 Restore

Product Type	Single Medicine Product	Effective Date	20/04/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Western herbal medicine to enhance/promote energy levels
- Traditionally used in Chinese medicine to maintain/support vitality
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to rejuvenating tonic
- Maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to maintain/support nail health/strength/thickness
- Anti-inflammatory/relieve inflammation
- Traditionally used in Ayurvedic medicine to maintain/support adrenal gland health
- Traditionally used in Western herbal medicine to maintain/support adrenal gland health
- Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal pain/discomfort
- Traditionally used in Western herbal medicine to maintain/support immune system health
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Aids/assists the body to cope with environmental stress
- Traditionally used in Ayurvedic medicine to enhance/promote body adaptation to stress
- Enhance/promote body adaptation to stress
- Support healthy stress response in the body
- Traditionally used in Chinese medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Decrease/reduce/relieve symptoms of stress
 - Linked indication - Decrease/reduce/relieve sleeplessness
 - Linked indication - Maintain/support healthy sexual function
 - Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
 - Linked indication - Enhance/improve/promote/increase short term memory
 - Linked indication - Enhance/promote energy levels

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Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
 Decrease/reduce/relieve symptoms of stress
 Enhance/improve/promote/increase short term memory
 Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
 Aid/assist/helps synthesis of neurotransmitters
 Maintain/support nervous system health
 Maintain/support nervous system function
 Decrease/reduce/relieve sleeplessness
 Traditionally used in Chinese medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
 Traditionally used in Chinese medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
 Traditionally used in Chinese medicine to decrease/reduce feelings of aggression/irritability associated with premenstrual tension
 Traditionally used in Chinese medicine to decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
 Traditionally used in Chinese medicine to decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
 Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of premenstrual tension
 Traditionally used in Chinese medicine to female tonic
 Maintain/support healthy sexual function
 Traditionally used in Chinese medicine to helps enhance/promote skin health
 Traditionally used in European herbal medicine to maintain/support skin health
 Maintain/support skin health

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to gastro oesophageal reflux disease.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to any adrenal related diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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

Ocimum tenuiflorum	600 mg
Olea europaea	80 mg
Paeonia lactiflora root Extract dry concentrate	150 mg
Equivalent: Paeonia lactiflora (Dry)	3 g
Withania somnifera root Extract dry concentrate	75 mg
Equivalent: Withania somnifera (Dry)	1.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

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Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose

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