



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214219	He Men's Midlife Formula
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	5/09/2013	
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 . He Men's Midlife Formula

Product Type	Single Medicine Product	Effective Date	22/01/2020
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Permitted Indications

- Traditionally used in Chinese medicine to enhance/promote energy levels
- Enhance/promote energy levels
- Traditionally used in Chinese medicine to helps enhance/promote/increase vitality
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support immune system health
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress
- Enhance/promote body adaptation to stress
- Traditionally used in Chinese medicine to relieve irritability
- Traditionally used in Chinese medicine to soothe/calm nerves
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Chinese medicine to decrease/reduce mental/cognitive fatigue
- Enhance/improve/promote/increase cognitive performance
- Traditionally used in Chinese medicine to enhance/improve/promote/increase cognitive performance
- Maintain/support cognitive function/mental function
- Traditionally used in Chinese medicine to support healthy emotional/mood balance
- Aphrodisiac/Enhance/improve/promote healthy libido
- Traditionally used in Chinese medicine to aphrodisiac/Enhance/improve/promote healthy libido

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Traditionally used in Chinese medicine to maintain/support healthy libido
 Maintain/support healthy libido
 Maintain/support healthy sexual function
 Traditionally used in Chinese medicine to male tonic
 Help maintain/support healthy prostate function
 Helps enhance/promote prostate health
 Maintain/support prostate health
 Maintain/support semen health
 Maintain/support urogenital health
 Traditionally used in Chinese medicine to maintain/support urogenital health
 Traditionally used in Chinese medicine to renal tonic/Enhance bladder health
 Relieve urinary frequency

Indication Requirements

Product presentation must not imply or refer to kidney disease.
 Product presentation must not imply or refer to serious immunological diseases.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to disease in any body organ.
 Product presentation must not imply or refer to infertility.
 Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.
 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).

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

Epimedium sagittatum leaf Extract dry concentrate	100 mg
Equivalent: Epimedium sagittatum (Dry)	1.5 g
Lycopersicon esculentum fruit Extract dry concentrate standardised	41.65 mg
Equivalent: Lycopersicon esculentum (Dry)	833 mg
Morinda officinalis root Extract dry concentrate	600 mg
Equivalent: Morinda officinalis (Dry)	3 g
Panax ginseng root Extract dry concentrate	150 mg
Equivalent: Panax ginseng (Dry)	1.5 g
Schisandra chinensis fruit Extract dry concentrate	150 mg
Equivalent: Schisandra chinensis (Dry)	750 mg
Serenoa repens fruit Extract dry concentrate	50 mg

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Equivalent: <i>Serenoa repens</i> (Dry)	500 mg
zinc amino acid chelate	30 mg
Equivalent: zinc	6 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
d-alpha-tocopherol
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose

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