



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

## Public Summary

<b>Summary for ARTG Entry:</b>	214219	He Men's Midlife Formula
<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>	5/09/2013	
<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 . He Men's Midlife Formula

<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 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 disease in any body organ.  
Product presentation must not imply or refer to chronic fatigue syndrome.  
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 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

#### Components

##### 1 . Formulation 1

**Dosage Form**                      Tablet, film coated  
**Route of Administration**      Oral

##### Visual Identification

#### Active Ingredients

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



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