



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	350161	Rest&Quiet Sleep 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>	30/11/2020	
<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.

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 . Rest&Quiet Sleep Formula**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/05/2021
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**Permitted Indications**

- Traditionally used in Bach flower remedies to calms the mind
- Traditionally used in Bach flower remedies to aid/assist/helps mind relaxation
- Traditionally used in Bach flower remedies to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Bach flower remedies to decrease/reduce/relieve symptoms of stress
- Traditionally used in Bach flower remedies to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Bach flower remedies to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Bach flower remedies to decrease/reduce/relieve mental overactivity
- Traditionally used in Bach flower remedies to decrease/reduce/relieve sleeplessness

**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 only refer to mild anxiety.

**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**

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

- 1 . Formulation 1

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**Dosage Form** Oral Liquid, solution

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Aesculus hippocastanum twig leafy flowering Tincture</b>	<b>25 nanolitre/mL</b>
Equivalent: Aesculus hippocastanum (Fresh)	250 ng/mL
<b>Agrimonia eupatoria twig leafy flowering Tincture</b>	<b>25 nanolitre/mL</b>
Equivalent: Agrimonia eupatoria (Fresh)	250 ng/mL
<b>Impatiens glandulifera twig leafy flowering Tincture</b>	<b>25 nanolitre/mL</b>
Equivalent: Impatiens glandulifera (Fresh)	250 ng/mL
<b>Prunus cerasifera twig leafy flowering Tincture</b>	<b>25 nanolitre/mL</b>
Equivalent: Prunus cerasifera (Fresh)	1.25 microgram/mL
<b>Ulmus minor twig leafy flowering Tincture</b>	<b>25 nanolitre/mL</b>
Equivalent: Ulmus minor (Fresh)	1.25 microgram/mL
<b>Verbena officinalis twig leafy flowering Tincture</b>	<b>25 nanolitre/mL</b>
Equivalent: Verbena officinalis (Fresh)	250 ng/mL

**Other Ingredients (Excipients)**

glycerol

Grapefruit

purified water

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