



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350161	Rest&Quiet Sleep Formula
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	30/11/2020	
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.

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

Product Type	Single Medicine Product	Effective Date	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.
- Product presentation must only refer to mild anxiety.
- Label statement: If symptoms persist, talk to your health professional.

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

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Dosage Form Oral Liquid, solution

Route of Administration Oral

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

glycerol

Grapefruit

purified water

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