



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350160	Rest&Quiet Calm 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'.

Sponsors must confirm the absence of aristolochic acids, in all medicines containing herbal material derived from any of the following plant genera - Akebia, Asarum, Bragantia, Clematis, Cocculus, Diploclisia, Menispermum, Saussurea, Sinomenium, Stephania, Vladimiria. The confirmation must be undertaken by chemical analysis using Liquid Chromatography Mass Spectrometry (LC-MS). The methodology used should adhere to best practice according to contemporary scientific literature. Confirmatory evidence is to be provided to the Director of Listing Compliance, Complementary and OTC Medicines Branch, prior to supply of each batch in Australia. The evidence submitted to the TGA is to include the certificate of analysis, all relevant details of the methodology, such as analytical method validation data, and the raw results. All supporting evidence must be approved by the TGA prior to supply of the batch in Australia.

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 Calm 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 soothe/calm nerves
- 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 maintain/support mental concentration/focus/clarity
- Traditionally used in Bach flower remedies to decrease/reduce/relieve mental overactivity

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

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Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

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
Clematis vitalba twig leafy flowering Tincture	25 nanolitre/mL
Equivalent: Clematis vitalba (Fresh)	250 ng/mL
Helianthemum nummularium twig leafy flowering Tincture	25 nanolitre/mL
Equivalent: Helianthemum nummularium (Fresh)	250 ng/mL
Impatiens glandulifera twig leafy flowering Tincture	25 nanolitre/mL
Equivalent: Impatiens glandulifera (Fresh)	250 ng/mL
Mimulus guttatus twig leafy flowering Tincture	25 nanolitre/mL
Equivalent: Mimulus guttatus (Fresh)	250 ng/mL
Ornithogalum umbellatum twig leafy flowering Tincture	25 nanolitre/mL
Equivalent: Ornithogalum umbellatum (Fresh)	1.25 microgram/mL
Populus tremula twig leafy flowering Tincture	25 nanolitre/mL
Equivalent: Populus tremula (Fresh)	1.25 microgram/mL
Prunus cerasifera twig leafy flowering Tincture	25 nanolitre/mL
Equivalent: Prunus cerasifera (Fresh)	1.25 microgram/mL

Other Ingredients (Excipients)

glycerol

Grapefruit

purified water

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