



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

## Public Summary

|                                |  |                          |
|--------------------------------|--|--------------------------|
| <b>Summary for ARTG Entry:</b> | 351614   | Rest&Quiet Focus 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<br>Australia |                          |
| <b>ARTG Start Date</b>         | 11/12/2020   |                          |
| <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'.

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 Focus Formula

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 26/10/2021 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

- Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support (state vitamin/mineral) within normal range
- 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 symptoms of mild anxiety
- Traditionally used in Bach flower remedies to decrease/reduce mental/cognitive fatigue
- Traditionally used in Bach flower remedies to maintain/support mental concentration/focus/clarity
- Traditionally used in Bach flower remedies to maintain/support cognitive function/mental function
- 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

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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.

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Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

**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> |
|------------------|------------------------|

**Components**

**1 . Formulation 1**

**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>Carpinus betulus twig leafy flowering Tincture</b>       | <b>25 nanolitre/mL</b> |
| Equivalent: Carpinus betulus (Fresh)                        | 1.25 microgram/mL      |
| <b>Clematis vitalba twig leafy flowering Tincture</b>       | <b>25 nanolitre/mL</b> |
| Equivalent: Clematis vitalba (Fresh)                        | 250 ng/mL              |
| <b>Juglans regia twig leafy flowering Tincture</b>          | <b>25 nanolitre/mL</b> |
| Equivalent: Juglans regia (Fresh)                           | 1.25 microgram/mL      |
| <b>Larix decidua twig leafy flowering Tincture</b>          | <b>25 nanolitre/mL</b> |
| Equivalent: Larix decidua (Fresh)                           | 1.25 microgram/mL      |
| <b>mecobalamin (co-methylcobalamin)</b>                     | <b>3 microgram/mL</b>  |
| <b>Scleranthus annuus twig leafy flowering Tincture</b>     | <b>25 nanolitre/mL</b> |
| Equivalent: Scleranthus annuus (Fresh)                      | 250 ng/mL              |
| <b>Ulmus minor twig leafy flowering Tincture</b>            | <b>25 nanolitre/mL</b> |
| Equivalent: Ulmus minor (Fresh)                             | 1.25 microgram/mL      |

**Other Ingredients (Excipients)**

- glycerol
- Grapefruit
- purified water

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