



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

## Public Summary

|                                |   |                     |
|--------------------------------|---|---------------------|
| <b>Summary for ARTG Entry:</b> | 199607  | METAGENICS RESILIAN |
| <b>ARTG entry for</b>          | Medicine Listed                                 |                     |
| <b>Sponsor</b>                 | Metagenics (Aust) Pty Ltd                       |                     |
| <b>Postal Address</b>          | PO Box 675, VIRGINIA BC, QLD, 4014<br>Australia |                     |
| <b>ARTG Start Date</b>         | 29/07/2012                                      |                     |
| <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.

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 . METAGENICS RESILIAN

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 22/02/2020 |
|---------------------|-------------------------|-----------------------|------------|

#### Permitted Indications

- Maintain/support physical endurance/capacity/stamina
- Traditionally used in Chinese medicine to help maintain/support emotional wellbeing
- Traditionally used in Chinese medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of stress
  - Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of stress
  - Linked indication - Decrease/reduce/relieve nervous tension/unrest
  - Linked indication - Decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support mental concentration/focus/clarity
- Maintain/support nervous system function
- Traditionally used in Chinese medicine to support healthy emotional/mood balance
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep

#### Indication Requirements

- Product presentation must not imply or refer to chronic fatigue syndrome.
- 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



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**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** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

|   |                |
|---|----------------|
| <b>Angelica polymorpha root Extract dry concentrate</b>               | <b>49.5 mg</b> |
| Equivalent: Angelica polymorpha (Dry)                                 | 495 mg         |
| <b>Astragalus membranaceus root Extract dry concentrate</b>           | <b>49.5 mg</b> |
| Equivalent: Astragalus membranaceus (Dry)                             | 495 mg         |
| <b>Atractylodes macrocephala rhizome Extract dry concentrate</b>      | <b>49.5 mg</b> |
| Equivalent: Atractylodes macrocephala (Dry)                           | 495 mg         |
| <b>Bupleurum falcatum root Extract dry concentrate</b>                | <b>49.5 mg</b> |
| Equivalent: Bupleurum falcatum (Dry)                                  | 495 mg         |
| <b>Citrus reticulata fruit peel Extract dry concentrate</b>           | <b>15 mg</b>   |
| Equivalent: Citrus reticulata (Dry)                                   | 150 mg         |
| <b>dimocarpus longan seed aril Extract dry concentrate</b>            | <b>49.5 mg</b> |
| Equivalent: dimocarpus longan (Dry)                                   | 495 mg         |
| <b>Gardenia jasminoides fruit Extract dry concentrate</b>             | <b>33 mg</b>   |
| Equivalent: Gardenia jasminoides (Dry)                                | 330 mg         |
| <b>Glycyrrhiza uralensis root and rhizome Extract dry concentrate</b> | <b>11.5 mg</b> |
| Equivalent: Glycyrrhiza uralensis (Dry)                               | 115 mg         |
| <b>Panax ginseng root and rhizome Extract dry concentrate</b>         | <b>49.5 mg</b> |
| Equivalent: Panax ginseng (Dry)                                       | 495 mg         |
| <b>Polygala sibirica root Extract dry concentrate</b>                 | <b>49.5 mg</b> |
| Equivalent: Polygala sibirica (Dry)                                   | 495 mg         |
| <b>Wolfiporia cocos fruiting body Extract dry concentrate</b>         | <b>49.5 mg</b> |
| Equivalent: Wolfiporia cocos (Dry)                                    | 495 mg         |
| <b>Zingiber officinale rhizome Extract dry concentrate</b>            | <b>12 mg</b>   |
| Equivalent: Zingiber officinale (Fresh)                               | 120 mg         |
| <b>Ziziphus jujuba fruit Extract dry concentrate</b>                  | <b>33 mg</b>   |
| Equivalent: Ziziphus jujuba (Dry)                                     | 330 mg         |
| <b>Ziziphus jujuba var. spinosa seed Extract dry concentrate</b>      | <b>49.5 mg</b> |
| Equivalent: Ziziphus jujuba var. spinosa (Dry)                        | 495 mg         |

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
disodium edetate  
gellan gum  
hypromellose  
magnesium stearate  
potable water  
potassium acetate

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