



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

## Public Summary

|                                |   |                    |
|--------------------------------|---|--------------------|
| <b>Summary for ARTG Entry:</b> | 192511  | METAGENICS RELAXAN |
| <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>         | 1/12/2011                                       |                    |
| <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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 RELAXAN

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 14/02/2020 |
|---------------------|-------------------------|-----------------------|------------|

#### Permitted Indications

Traditionally used in Chinese medicine to relieve irritability  
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 nervous tension/unrest  
Traditionally used in Chinese medicine to support healthy emotional/mood balance  
Traditionally used in Chinese medicine to maintain/support/regulate healthy menstrual cycle

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

#### Additional Product information



Australian Government  
Department of Health  
Therapeutic Goods Administration

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>63.2 mg</b> |
| Equivalent: Angelica polymorpha (Dry)                                 | 632 mg         |
| <b>Atractylodes macrocephala rhizome Extract dry concentrate</b>      | <b>63.2 mg</b> |
| Equivalent: Atractylodes macrocephala (Dry)                           | 632 mg         |
| <b>Bupleurum falcatum root Extract dry concentrate</b>                | <b>75 mg</b>   |
| Equivalent: Bupleurum falcatum (Dry)                                  | 750 mg         |
| <b>Cyperus rotundus rhizome Extract dry concentrate</b>               | <b>63.2 mg</b> |
| Equivalent: Cyperus rotundus (Dry)                                    | 632 mg         |
| <b>Gardenia jasminoides fruit Extract dry concentrate</b>             | <b>42.4 mg</b> |
| Equivalent: Gardenia jasminoides (Dry)                                | 424 mg         |
| <b>Glycyrrhiza uralensis root and rhizome Extract dry concentrate</b> | <b>31.8 mg</b> |
| Equivalent: Glycyrrhiza uralensis (Dry)                               | 318 mg         |
| <b>Mentha haplocalyx herb Extract dry concentrate</b>                 | <b>21.4 mg</b> |
| Equivalent: Mentha haplocalyx (Dry)                                   | 214 mg         |
| <b>Paeonia lactiflora root Extract dry concentrate</b>                | <b>63.2 mg</b> |
| Equivalent: Paeonia lactiflora (Dry)                                  | 632 mg         |
| <b>Paeonia suffruticosa root bark Extract dry concentrate</b>         | <b>42.4 mg</b> |
| Equivalent: Paeonia suffruticosa (Dry)                                | 424 mg         |
| <b>Wolfiporia cocos fruiting body Extract dry concentrate</b>         | <b>63.2 mg</b> |
| Equivalent: Wolfiporia cocos (Dry)                                    | 632 mg         |
| <b>Zingiber officinale rhizome Extract dry concentrate</b>            | <b>21 mg</b>   |
| Equivalent: Zingiber officinale (Fresh)                               | 210 mg         |

Other Ingredients (Excipients)

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

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