## **Australian Government**

### **Department of Health**

## Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 199607 METAGENICS RESILIAN

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 29/07/2012

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.

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

Product Type Single Medicine Product Effective Date 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 mental illnesses, disorders or conditions.

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

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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### This is not an ARTG Certificate document.

Produced at 31.08.2021 at 04:41:24 AEST



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## Warnings

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

## **Additional Product information**

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Pack Size Poison Schedule

### Components

### 1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

## **Active Ingredients**

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

### Other Ingredients (Excipients)

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

potable water

potassium acetate



## **Department of Health**

Therapeutic Goods Administration

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