# **Australian Government**

## **Department of Health**

## Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 369796 Anxiolift

ARTG entry for Medicine Listed

 Sponsor
 McPherson's Consumer Products Pty Ltd

 Postal Address
 Locked Bag 5018, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 18/06/2021

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.

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. Anxiolift

Product Type Single Medicine Product Effective Date 10/02/2022

### **Permitted Indications**

Traditionally used in Avurvedic medicine to rasavan/reiuvenative tonic

Traditionally used in Chinese medicine to regulate Qi

Traditionally used in Chinese medicine to calm/stabilise/settle/regulate shen

Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal bloating/distention

Traditionally used in Chinese medicine to decrease/reduce/relieve abdominal feeling of fullness

Traditionally used in Chinese medicine to relieve excessive belching

Traditionally used in Chinese medicine to digestive tonic/Improve digestive weakness

Traditionally used in Chinese medicine to decrease/reduce/relieve nausea

Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress

Enhance/promote body adaptation to stress

Traditionally used in Ayurvedic medicine to enhance/promote body adaptation to stress

Traditionally used in Ayurvedic medicine to support healthy stress response in the body

Traditionally used in Chinese medicine to relieve irritability

Traditionally used in Chinese medicine to calms the mind

Traditionally used in Chinese medicine to aid/assist/helps mind relaxation

Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit

Traditionally used in Chinese medicine to decrease/reduce/relieve restlessness/excess nervous energy

Decrease/reduce/relieve symptoms of stress

Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress

Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety

Decrease/reduce/relieve symptoms of mild anxiety

# Indication Requirements

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If symptoms persist, talk to your health professional.

If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for

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you.

Product presentation must only refer to mild anxiety.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

### **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**

#### Pack Size/Poison information

Pack Size Poison Schedule

## Components

## 1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Ora

### Visual Identification

### **Active Ingredients**

Citrus reticulata fruit peel Extract dry concentrate	75 mg
Equivalent: Citrus reticulata (Dry)	750 mg
Magnolia officinalis stem bark Extract dry concentrate standardised	93.75 mg
Equivalent: honokiol (of Magnolia officinalis) ()	8.4375 mg
Equivalent: Magnolia officinalis ()	750 mg
Ocimum tenuiflorum whole plant Extract dry concentrate standardised	300 mg
Equivalent: Ocimum tenuiflorum (Dry)	3000 mg
Polygala tenuifolia root Extract dry concentrate	75 mg
Equivalent: Polygala tenuifolia (Dry)	750 mg
Withania somnifera root Extract dry concentrate	187.5 mg
Equivalent: Withania somnifera (Dry)	1.875 g
Wolfiporia cocos fruiting body Extract dry concentrate	100 mg
Equivalent: Wolfiporia cocos (Dry)	500 mg

### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

hypromellose

macrogol 8000

magnesium stearate

maltodextrin

microcrystalline cellulose

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