



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|------------|
| Summary for ARTG Entry: | 377418 | SaffroMind |
| ARTG entry for | Medicine Listed | |
| Sponsor | Bio Concepts Pty Ltd | |
| Postal Address | PO Box 190, Banyo, Brisbane, QLD, 4014 Australia | |
| ARTG Start Date | 3/11/2021 | |
| 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 . SaffroMind

| Product Type | Single Medicine Product | Effective Date | 3/11/2021 |
|--------------|-------------------------|----------------|-----------|
|--------------|-------------------------|----------------|-----------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Decrease/reduce/relieve mild joint pain/soreness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of nervous indigestion
- Help maintain/support emotional wellbeing
- Decrease/reduce/relieve restlessness/excess nervous energy
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety
- Support healthy emotional/mood balance
- Maintains/supports refreshing sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Indication Requirements

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

- Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

| | |
|---|---------------|
| Crocus sativus stigma Extract dry concentrate | 15 mg |
| Equivalent: Crocus sativus (Dry) | 75 mg |
| Curcuma longa rhizome Extract dry concentrate standardised | 250 mg |
| Equivalent: Curcuma longa (Dry) | 7.812 g |
| Lavender Oil | 80 mg |

Other Ingredients (Excipients)

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary