



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|----------------|
| Summary for ARTG Entry: | 363302 | Adrenal Elixir |
| ARTG entry for | Medicine Listed | |
| Sponsor | Greal Labs Pty Ltd | |
| Postal Address | PO Box 193, Fitzroy, VIC, 3065 Australia | |
| ARTG Start Date | 27/04/2021 | |
| 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 . Adrenal Elixir

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 27/04/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support energy levels
Traditionally used in Ayurvedic medicine to maintain/support healthy adrenal gland function
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
Enhance/promote body adaptation to stress
Decrease/reduce/relieve symptoms of stress
Decrease/reduce/relieve symptoms of mild anxiety
Enhance/improve/promote/increase cognitive performance
Maintain/support cognitive function/mental function
Support healthy emotional/mood balance
Maintain/support healthy sexual function in healthy females

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.
Product presentation must not imply or refer to any adrenal related diseases.
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

Warnings

Contains lactose (or words to that effect).
If you are pregnant, or considering becoming pregnant, do not take without consulting a health professional' (or words to that effect).

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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

| | |
|--|---------------|
| Eleutherococcus senticosus root Extract dry concentrate | 150 mg |
| Equivalent: Eleutherococcus senticosus (Dry) | 3 g |
| Ocimum tenuiflorum leaf Extract dry concentrate | 100 mg |
| Equivalent: Ocimum tenuiflorum (Dry) | 1.3 g |
| Rhodiola rosea root Extract dry concentrate | 170 mg |
| Equivalent: Rhodiola rosea (Dry) | 1.7 g |
| Withania somnifera root Extract dry concentrate | 300 mg |
| Equivalent: Withania somnifera (Dry) | 3.75 g |

Other Ingredients (Excipients)

Acacia

colloidal anhydrous silica

hypromellose

lactose

Oryza sativa

purified water

Sunflower Oil

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