



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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
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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 only refer to mild anxiety.
Product presentation must not imply or refer to any adrenal related diseases.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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