



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|-------------|
| Summary for ARTG Entry: | 373634 | AdrenaForte |
| ARTG entry for | Medicine Listed | |
| Sponsor | RN Labs Pty Ltd | |
| Postal Address | 18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia | |
| ARTG Start Date | 27/08/2021 | |
| 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 . AdrenaForte

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 27/08/2021 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Enhance/promote/physical endurance/capacity/stamina
Enhance/promote body adaptation to stress
Enhance/improve/promote/increase cognitive performance
Maintain/support general mental wellbeing
Maintain/support nervous system health

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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

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Active Ingredients

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|--|---------------|
| Ginkgo biloba leaf Extract dry concentrate | 100 mg |
| Equivalent: Ginkgo biloba (Dry) | 5 g |
| Glycyrrhiza glabra root Extract dry concentrate | 75 mg |
| Equivalent: Glycyrrhiza glabra (Dry) | 600 mg |
| Panax ginseng root Extract dry concentrate | 200 mg |
| Equivalent: Panax ginseng (Dry) | 2 g |
| sodium ascorbate | 113 mg |
| Equivalent: ascorbic acid | 100 mg |

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
leucine
silicified microcrystalline cellulose

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