Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

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	

Active Ingredients	
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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