



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	373633	Adaptex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	RN Labs Pty Ltd	
<b>Postal Address</b>	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
<b>ARTG Start Date</b>	27/08/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Adaptex

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/08/2021
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

Enhance/promote/physical endurance/capacity/stamina  
Maintain/support immune system health  
Enhance/promote body adaptation to stress  
Support healthy stress response in the body  
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 serious immunological diseases.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
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

No Warnings included on Record

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

#### Components

1 . Formulation 1

Public Summary



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Centella asiatica whole plant Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Centella asiatica (Dry)	1 g
<b>Eleutherococcus senticosus root and rhizome Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Eleutherococcus senticosus (Dry)	2.25 g
<b>Ocimum tenuiflorum leaf Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Ocimum tenuiflorum (Dry)	1 g
<b>Rhodiola rosea root Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Rhodiola rosea (Dry)	800 mg
<b>Withania somnifera root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Withania somnifera (Dry)	4 g

**Other Ingredients (Excipients)**

colloidal anhydrous silica

hypromellose

leucine

maltodextrin

silicified microcrystalline cellulose

© 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