



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	320568	ADRENAL RX
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	ATP Science Pty Ltd	
<b>Postal Address</b>	5/63-69 Meakin Road, Meadowbrook, QLD, 4131 Australia	
<b>ARTG Start Date</b>	23/07/2019	
<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 . ADRENAL RX

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/06/2021
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#### Permitted Indications

Anti-inflammatory/relieve inflammation  
Support healthy stress response in the body  
Decrease/reduce/relieve symptoms of stress  
Decrease/reduce/relieve symptoms of mild anxiety  
Maintain/support general mental wellbeing  
Support healthy emotional/mood balance  
Maintains/supports refreshing sleep  
Maintain/support healthy sleeping patterns

#### Indication Requirements

Product presentation must only refer to mild anxiety.  
Label statement: If symptoms persist, talk to your health professional.  
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

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1



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**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Curcuma longa rhizome Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Curcuma longa (Dry)	2.5 g
<b>Rhodiola rosea root Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Rhodiola rosea (Dry)	1 g
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Schisandra chinensis (Dry)	4 g
<b>Withania somnifera root Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Withania somnifera (Dry)	1 g

**Other Ingredients (Excipients)**

Acacia  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
purified water

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