



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

## Public Summary

<b>Summary for ARTG Entry:</b>	370559	ADAPTOGEN TONIC+
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Ora Health Pty Ltd	
<b>Postal Address</b>	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
<b>ARTG Start Date</b>	5/07/2021	
<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 . ADAPTOGEN TONIC+

Product Type	Single Medicine Product	Effective Date	5/07/2021
--------------	-------------------------	----------------	-----------

### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support natural liver cleansing/detoxification processes
- Traditionally used in Chinese medicine to engender Fluid
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to warm and nourish/strengthen/tonify/enrich kidneys/kidney-yang
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence
- Maintain/support energy production
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness in healthy elderly individuals
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support eye health
- Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
- Maintain/support healthy growth and development
- Traditionally used in Western herbal medicine to restorative tonic
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis

Public Summary



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

Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support immune system health  
Traditionally used in Western herbal medicine to maintain/support healthy immune system function  
Maintain/support healthy immune system function  
Traditionally used in Western herbal medicine to maintain/support immune system to fight illness  
Maintain/support muscle function  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Helps decrease/reduce homocysteine levels in healthy individuals  
Aid/assist/helps protein synthesis in the body  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress  
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress  
Traditionally used in Ayurvedic medicine to support healthy stress response in the body  
Support healthy stress response in the body  
Help maintain/support emotional wellbeing  
Traditionally used in Chinese medicine to help maintain/support emotional wellbeing  
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress  
Traditionally used in Western herbal medicine to maintain/support mental concentration/focus/clarity  
Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function  
Traditionally used in Western herbal medicine to maintain/support cognitive function/mental function  
Traditionally used in Ayurvedic medicine to maintain/support general mental wellbeing  
Maintain/support general mental wellbeing  
Maintain/support nerve conduction  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Traditionally used in Chinese medicine to maintain/support nervous system health  
Traditionally used in Ayurvedic medicine to maintain/support nervous system health  
Traditionally used in Western herbal medicine to maintain/support nervous system health  
Maintain/support nervous system function  
Traditionally used in Chinese medicine to maintain/support nervous system function  
Traditionally used in Ayurvedic medicine to maintain/support nervous system function  
Support healthy emotional/mood balance  
Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness  
Traditionally used in Chinese medicine to maintain/support healthy sleeping patterns  
Traditionally used in Ayurvedic medicine to maintain/support healthy sleeping patterns  
Traditionally used in Ayurvedic medicine to maintain/support reproductive system health in healthy males  
Traditionally used in Chinese medicine to maintain/support lung health  
Maintain/support skin health  
Maintain/support wound healing in healthy individuals  
Maintain/support skin repair/healing/regeneration in healthy individuals  
Traditionally used in Chinese medicine to maintain/support urinary tract health  
Traditionally used in Chinese medicine to maintain/support urinary tract function  
Traditionally used in Chinese medicine to maintain/support urogenital health  
Traditionally used in Chinese medicine to maintain/support kidney function  
Traditionally used in Chinese medicine to maintain/support kidney 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 kidney disease.  
If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.



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

Public Summary

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to chronic fatigue syndrome.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to drugs/alcohol.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

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

**Components**

**1 . Formulation 1**

**Dosage Form**                      Capsule, hard

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>calcium folinate</b>	<b>220 microgram</b>
Equivalent: folic acid	200 microgram
<b>calcium pantothenate</b>	<b>54.59 mg</b>
Equivalent: pantothenic acid	50 mg
<b>Crocus sativus stigma Extract dry concentrate</b>	<b>14 mg</b>
Equivalent: Crocus sativus (Dry)	42 mg
<b>Eleutherococcus senticosus root Extract dry concentrate</b>	<b>33.33 mg</b>
Equivalent: Eleutherococcus senticosus (Dry)	1.5 g
<b>Glycyrrhiza glabra root Extract dry concentrate</b>	<b>76.923 mg</b>
Equivalent: Glycyrrhiza glabra (Dry)	1 g
<b>mecobalamin</b>	<b>100 microgram</b>
<b>nicotinamide</b>	<b>50 mg</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>5 mg</b>
Equivalent: pyridoxine	3.19 mg
<b>pyridoxine hydrochloride</b>	<b>10 mg</b>
Equivalent: pyridoxine	8.23 mg
<b>riboflavin</b>	<b>10 mg</b>



**Australian Government**

**Department of Health and Aged Care**

Therapeutic Goods Administration

<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>40 mg</b>
Equivalent: Schisandra chinensis (Dry)	1 g
<b>thiamine hydrochloride</b>	<b>25.42 mg</b>
Equivalent: thiamine	20 mg
<b>Withania somnifera root Extract dry concentrate</b>	<b>125 mg</b>
Equivalent: Withania somnifera (Dry)	1.5 g

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
disodium edetate  
gellan gum  
hypromellose  
leucine  
maltodextrin  
potable water  
potassium acetate  
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