



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

## Public Summary

<b>Summary for ARTG Entry:</b>	300516	Astragalus 8
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	McPherson's Consumer Products Pty Ltd	
<b>Postal Address</b>	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
<b>ARTG Start Date</b>	8/03/2018	
<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 . Astragalus 8

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	9/11/2020
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### Permitted Indications

- Traditionally used in Chinese medicine to stabilise Exterior
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify lungs/lung-qi
- Traditionally used in Chinese medicine to support protective qi
- Traditionally used in Chinese medicine to helps enhance/promote/increase vitality
- Traditionally used in Chinese medicine to restorative tonic
- Traditionally used in Chinese medicine to maintain/support immune system health
- Traditionally used in Western herbal medicine to enhance/improve/promote immune defence/immunity
- Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity
- Traditionally used in Western herbal medicine to helps enhance/improve/promote immune system function
- Traditionally used in Western herbal medicine to maintain/support immune system to fight illness
- Traditionally used in Chinese medicine to maintain/support immune system to fight illness
- Traditionally used in Western herbal medicine to helps stimulate a healthy immune system response
- Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress
- Traditionally used in Chinese medicine to helps reduce occurrence of common colds

### Indication Requirements

- 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.
- Product presentation must not imply or refer to serious immunological diseases.
- 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 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



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No Specific Indications included on Record

**Warnings**

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

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Astragalus membranaceus root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Astragalus membranaceus (Dry)	3 g
<b>Atractylodes macrocephala root Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Atractylodes macrocephala (Dry)	750 mg
<b>Codonopsis pilosula root Extract dry concentrate</b>	<b>150 mg</b>
Equivalent: Codonopsis pilosula (Dry)	750 mg
<b>Eleutherococcus senticosus root Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Eleutherococcus senticosus (Dry)	450 mg
<b>Ganoderma lucidum fruiting body Extract dry concentrate</b>	<b>65 mg</b>
Equivalent: Ganoderma lucidum (Dry)	650 mg
<b>Glycyrrhiza uralensis root and stolon Extract dry concentrate</b>	<b>20 mg</b>
Equivalent: Glycyrrhiza uralensis (Dry)	100 mg
<b>Ligustrum lucidum fruit Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Ligustrum lucidum (Dry)	1000 mg
<b>Schisandra chinensis fruit Extract dry concentrate</b>	<b>60 mg</b>
Equivalent: Schisandra chinensis (Dry)	300 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate  
 Carnuba Wax  
 colloidal anhydrous silica  
 croscarmellose sodium  
 hypromellose  
 macrogol 400  
 magnesium stearate  
 maltodextrin  
 microcrystalline cellulose

Public Summary

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