



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

## Public Summary

<b>Summary for ARTG Entry:</b>	376615	Kids' Astragalus 8 Immune Shield
<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>	20/10/2021	
<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 . Kids' Astragalus 8 Immune Shield

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	20/10/2021
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### Permitted Indications

- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood
- 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 support protective qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify/invigorate spleen
- Traditionally used in Chinese medicine to release exterior/exogenous wind-coldness
- Traditionally used in Chinese medicine to dispel/expel/extinguish/disperse/clear wind-heat
- Traditionally used in Chinese medicine to helps enhance/promote/increase vitality
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to decrease/reduce/relieve loss of appetite
- Maintain/support healthy appetite
- Maintain/support immune system health
- Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity
- Maintain/support healthy immune system function
- Helps reduce occurrence of common colds
- Traditionally used in Chinese medicine to helps reduce occurrence of common colds
- 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.

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

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

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

Product presentation must not imply or refer to disease in any body organ.



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Product presentation must not imply or refer to eating disorders.

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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Astragalus membranaceus root Extract dry concentrate</b>	<b>20.54 mg/mL</b>
Equivalent: Astragalus membranaceus (Dry)	308.1 mg/mL
<b>Atractylodes macrocephala root Extract dry concentrate</b>	<b>20.54 mg/mL</b>
Equivalent: Atractylodes macrocephala (Dry)	102.7 mg/mL
<b>Sambucus nigra fruit Juice concentrate</b>	<b>17.921 mg/mL</b>
Equivalent: Sambucus nigra (Fresh)	215.05 mg/mL
<b>Saposhnikovia divaricata root Extract dry concentrate</b>	<b>20.54 mg/mL</b>
Equivalent: Saposhnikovia divaricata (Dry)	102.7 mg/mL
<b>zinc gluconate</b>	<b>2.16 mg/mL</b>
Equivalent: zinc	.28 mg/mL

**Other Ingredients (Excipients)**

citric acid

d-alpha-tocopheryl acetate

Flavour

glycerol

maltodextrin

potassium sorbate

purified water

Stevia rebaudiana

xanthan gum

Public Summary

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