

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 300515 Astragalus 8

ARTG entry for Medicine Listed

 Sponsor
 McPherson's Consumer Products Pty Ltd

 Postal Address
 Locked Bag 5018, Kingsgrove, NSW, 2208

Australia

ARTG Start Date 8/03/2018
Product Category Medicine
Status Active

Approval Area 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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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

Product Type Single Medicine Product Effective Date 25/06/2020

Permitted Indications

Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi

Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence

Traditionally used in Chinese medicine to helps enhance/promote/increase vitality

Traditionally used in Western herbal medicine to relieve weariness/firedness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function

Traditionally used in Chinese medicine to maintain/support immune system to fight illness

Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress

Support healthy stress response in the body

Traditionally used in Chinese medicine to helps reduce occurrence of common colds

Indication Requirements

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

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

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information	on		
Pack Size		Poison Schedule	
Components			
1 . Formulation 1			
Dosage Form	Oral Liquid		
Route of Administration	Oral		
Visual Identification			
Active Ingredients			
Astragalus membranaceus root Extract liquid			144 mg/mL
Equivalent: Astragalus membranaceus (Dry)			144 mg/mL
Atractylodes macrocephala rhizome Extract liquid			57 mg/mL
Equivalent: Atractylodes macrocephala (Dry)			57 mg/mL
Codonopsis pilosula root Extract liquid			57 mg/mL
Equivalent: Codonopsis pilosula (Dry)			57 mg/mL

57 mg/mL
57 mg/mL
3.75 mg/mL
15 mg/mL
85 mg/mL
85 mg/mL
35 mg/mL
35 mg/mL

Other Ingredients (Excipients)

Eleutherococcus senticosus root Extract liquid

Equivalent: Eleutherococcus senticosus (Dry)

ethanol glycerol purified water Spearmint oil

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50 mg/mL

50 mg/mL