



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	300515	Astragalus 8
ARTG entry for	Medicine Listed	
Sponsor	Global Therapeutics Pty Ltd	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 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
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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/tiredness/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

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 mental illnesses, disorders or conditions.
Product presentation must not imply or refer to chronic fatigue syndrome.
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 words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Astragalus membranaceus	144 mg/mL
Equivalent: Astragalus membranaceus	144 mg/mL
Atractylodes macrocephala	57 mg/mL
Equivalent: Atractylodes macrocephala	57 mg/mL
Codonopsis pilosula	57 mg/mL
Equivalent: Codonopsis pilosula	57 mg/mL
Eleutherococcus senticosus	50 mg/mL
Equivalent: Eleutherococcus senticosus	50 mg/mL
Ganoderma lucidum	57 mg/mL
Equivalent: Ganoderma lucidum	57 mg/mL
Glycyrrhiza uralensis	3.75 mg/mL
Equivalent: Glycyrrhiza uralensis	15 mg/mL
Ligustrum lucidum	85 mg/mL
Equivalent: Ligustrum lucidum	85 mg/mL
Schisandra chinensis	35 mg/mL
Equivalent: Schisandra chinensis	35 mg/mL

Other Ingredients (Excipients)

ethanol

glycerol

purified water

Spearmint oil

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