



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

## Public Summary

<b>Summary for ARTG Entry:</b>	332481	METAGENICS SUPER MUSHROOM WITH ASTRAGALUS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	25/03/2020	
<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.

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 . METAGENICS SUPER MUSHROOM WITH ASTRAGALUS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/03/2020
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### Permitted Indications

- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Traditionally used in Chinese medicine to decrease/reduce excess mucous
- Traditionally used in Chinese medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Chinese medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
- Traditionally used in Chinese medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Chinese medicine to relieve symptoms of mild upper respiratory tract infections

### Indication Requirements

- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious immunological diseases.
- Respiratory tract infections must be qualified by 'mild'.
- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings



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Therapeutic Goods Administration

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

Adults only. OR Not to be used in children under two years of age without medical advice (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>600 mg</b>
Equivalent: Astragalus membranaceus (Dry)	6 g
<b>Ganoderma lucidum fruiting body Extract dry concentrate</b>	<b>176.47 mg</b>
Equivalent: Ganoderma lucidum (Dry)	3 g
<b>Trametes versicolor fruiting body Extract dry concentrate</b>	<b>327.27 mg</b>
Equivalent: Trametes versicolor (Dry)	9 g

**Other Ingredients (Excipients)**

croscarmellose sodium  
glycerol  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
silicon dioxide

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