



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	15/02/2023
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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 immunological diseases.
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
Label statement: If symptoms persist, talk to your health professional.
Respiratory tract infections must be qualified by 'mild'.
Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).
If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information



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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	
Astragalus membranaceus root Extract dry concentrate	600 mg
Equivalent: Astragalus membranaceus (Dry)	6 g
Ganoderma lucidum fruiting body Extract dry concentrate	176.47 mg
Equivalent: Ganoderma lucidum (Dry)	3 g
Trametes versicolor fruiting body Extract dry concentrate	327.27 mg
Equivalent: Trametes versicolor (Dry)	9 g
Other Ingredients (Excipients)	
croscarmellose sodium	
glycerol	
hypromellose	
magnesium stearate	
microcrystalline cellulose	
silicon dioxide	

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