



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	206805	METAGENICS SUPER MUSHROOM COMPLEX
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	8/03/2013	
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 COMPLEX

Product Type	Single Medicine Product	Effective Date	27/06/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Enhance/improve/promote immune defence/immunity
- Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function
- Traditionally used in Chinese medicine to maintain/support healthy immune system function
- 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 expectorant/clear respiratory tract mucous
- Traditionally used in Chinese medicine to relieve symptoms of mild upper respiratory tract infections

Indication Requirements

- 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 serious immunological diseases.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- 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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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

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Cordyceps sinensis hyphae Extract dry concentrate	98.77 mg/g
Equivalent: Cordyceps sinensis (Dry)	1.481 g/g
Ganoderma lucidum fruiting body Extract dry concentrate	87.15 mg/g
Equivalent: Ganoderma lucidum (Dry)	1.481 g/g
Lentinula edodes fruiting body Extract dry concentrate	92.59 mg/g
Equivalent: Lentinula edodes (Dry)	1.481 g/g
Trametes versicolor fruiting body Extract dry concentrate	53.87 mg/g
Equivalent: Trametes versicolor (Dry)	1.481 g/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

malic acid

maltodextrin

Steviol glycosides

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