



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	301609	MediHerb Mushroom Forte
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	5/04/2018 11:00:00 PM	
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 . MediHerb Mushroom Forte

Product Type	Single Medicine Product	Effective Date	4/03/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Blood
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/invigorate heart-blood
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish heart Qi
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish/fortify lungs/lung-qi
- Traditionally used in Chinese medicine to calm/stabilise/settle/regulate shen
- Maintain/support vitality
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to nourish the heart
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Traditionally used in Chinese medicine to clear/expel/dissolve/resolve Phlegm
- Traditionally used in Chinese medicine to decrease/reduce/relieve cough

Indication Requirements

- 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.
- 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 heart disease.
- 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.

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Product presentation must not imply or refer to serious cardiovascular conditions.

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

Do not take while on warfarin therapy without medical advice.

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

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Ganoderma lucidum mushroom Extract dry concentrate	62.5 mg
Equivalent: Ganoderma lucidum (Dry)	1 g
Grifola frondosa mushroom Extract dry concentrate	208.34 mg
Equivalent: Grifola frondosa (Dry)	833.36 mg
Lentinula edodes mushroom Extract dry concentrate	250 mg
Equivalent: Lentinula edodes (Dry)	1 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
hypromellose
magnesium stearate
microcrystalline cellulose
sodium starch glycollate

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