

**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	S	
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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
Permitted Indications			
Antioxidant/Reduce free	e radicals formed in the body		
Helps reduce/decrease	e free radical damage to body cells		
Traditionally used in Ch	ninese medicine to tonify/nourish/strengthen/replenish E	Blood	
Traditionally used in Ch	ninese medicine to tonify/nourish/strengthen/replenish/i	nvigorate heart-blood	
Traditionally used in Ch	ninese medicine to tonify/nourish/strengthen/replenish C	Qi	
Traditionally used in Ch	ninese medicine to tonify/nourish/strengthen/replenish h	neart Qi	
Traditionally used in Ch	ninese medicine to tonify/nourish/strengthen/replenish/f	ortify lungs/lung-qi	
Traditionally used in Ch	ninese medicine to calm/stabilise/settle/regulate shen		
Maintain/support vitality	4		
Traditionally used in Ch	ninese medicine to relieve weariness/tiredness/fatigue/f	eeling of weakness	
Maintain/support gener	al health and wellbeing		
Traditionally used in Ch	ninese medicine to nourish the heart		
Maintain/support immu	ne system health		
Maintain/support health	ny immune system function		
Maintain/support immu	ne system to fight illness		
Traditionally used in Ch	ninese medicine to clear/expel/dissolve/resolve Phlegm		
Traditionally used in Ch	ninese 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 serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza. Product presentation must not imply or refer to serious cardiovascular conditions.

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Product presentation must not imply or refer to serious immunological diseases.

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Product presentation must not imply or refer to heart disease.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Laber Statement. Aduits only, OR NOL to be used in children und	der z years of age without medical advice (of words to that effect).
tandard Indications	
lo Standard Indications included on Record	
pecific Indications	
lo Specific Indications included on Record	
Varnings	
o not take while on warfarin therapy without medical advice. symptoms persist consult your healthcare practitioner (or word or practitioner dispensing only.	ds to that effect).
dditional Product information	
ack Size/Poison information	
Pack Size	Poison Schedule
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	

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