

# **Australian Government**

# **Department of Health and Aged Care**

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 328045 SuperFeast Reishi

ARTG entry for Medicine Listed

 Sponsor
 JEMS Superfoods Pty Ltd trading as SuperFeast

 Postal Address
 2/16-18 towers drive, mullumbimby, NSW, 2482

Australia

ARTG Start Date 24/12/2019
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 . SuperFeast Reishi

Product Type Single Medicine Product Effective Date 2/01/2025

# 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 promote flow of Blood

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 relieve weariness/tiredness/fatigue/feeling of weakness

Traditionally used in Chinese medicine to maintain/support general health and wellbeing

Traditionally used in Chinese medicine to maintain/support cardiovascular system health

Traditionally used in Chinese medicine to helps maintain/support healthy heart function

Traditionally used in Chinese medicine to maintain/support healthy cardiovascular system function

Traditionally used in Chinese medicine to maintain/support heart health

Traditionally used in Chinese medicine to maintain/support healthy appetite

Traditionally used in Chinese medicine to helps regulate appetite

Traditionally used in Chinese medicine to maintain/support digestive system health

Traditionally used in Chinese medicine to maintain/support immune system health

Traditionally used in Chinese medicine to enhance/improve/promote immune defence/immunity

 $Traditionally \ used \ in \ Chinese \ medicine \ to \ helps \ enhance/improve/promote \ immune \ system \ function$ 

Traditionally used in Chinese medicine to maintain/support healthy immune system function

Traditionally used in Chinese medicine to maintain/support immune system to fight illness

Traditionally used in Chinese medicine to adaptogen/Help body adapt to stress Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit

Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Chinese medicine to enhance/improve/promote/increase sleep quality/deep sleep

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.

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

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

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).

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 eating disorders.

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

No Warnings included on Record

# **Additional Product information**

#### Pack Size/Poison information

Pack Size Poison Schedule

# Components

### 1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Ora

# Visual Identification

# Active Ingredients

Ganoderma lucidum mushroom Extract dry concentrate1 g/gEquivalent: Ganoderma lucidum (Dry)10 g/g

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