

## **Australian Government**

### **Department of Health**

## Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: 345510 SuperFeast Mushroom M8

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 7/10/2020
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 . SuperFeast Mushroom M8

**Product Type** Single Medicine Product **Effective Date** 7/10/2020

### **Permitted Indications**

Maintain/support immune system health

### **Indication Requirements**

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

### 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.

#### Additional Product information

### Pack Size/Poison information

Pack Size Poison Schedule

#### Components

#### 1 . Formulation 1

**Dosage Form** Capsule, hard

Route of Administration Oral

Visual Identification

**Active Ingredients** 

Cordyceps sinensis hyphae Extract dry concentrate

76.769 mg

Equivalent: Cordyceps sinensis (Dry)

767.69 mg

Ganoderma lucidum fruiting body Extract dry concentrate

76.769 mg

Page 1 of 2

Produced at 31.08.2021 at 01:01:56 AEST



# **Australian Government**

### **Department of Health**

# Therapeutic Goods Administration

Equivalent: Ganoderma lucidum (Dry)	767.69 mg
Grifola frondosa fruiting body Extract dry concentrate	76.769 mg
Equivalent: Grifola frondosa (Dry)	767.69 mg
Lentinula edodes fruiting body Extract dry concentrate	76.769 mg
Equivalent: Lentinula edodes (Dry)	767.69 mg
Polyporus umbellatus fruiting body Extract dry concentrate	38.385 mg
Equivalent: Polyporus umbellatus (Dry)	383.85 mg
Trametes versicolor fruiting body Extract dry concentrate	76.769 mg
Equivalent: Trametes versicolor (Dry)	767.69 mg
Tremella fuciformis fruiting body Extract dry concentrate	38.385 mg
Equivalent: Tremella fuciformis (Dry)	383.85 mg
Wolfiporia cocos fruiting body Extract dry concentrate	38.385 mg
Equivalent: Wolfiporia cocos (Dry)	383.85 mg

### Other Ingredients (Excipients)

hypromellose Phyllostachys nigra

purified water

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at http://www.tga.gov.au/about/website-copyright.htm.