Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 389294 Mushroom Matrix

ARTG entry for Medicine Listed

Sponsor Bio Concepts Pty Ltd

Postal Address PO Box 190, Banyo, Brisbane, QLD, 4014

Australia

ARTG Start Date 31/05/2022

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. Mushroom Matrix

Product Type Single Medicine Product Effective Date 31/05/2022

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 Qi

Traditionally used in Chinese medicine to maintain/support energy levels

Traditionally used in Chinese medicine to maintain/support vitality

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

Maintain/support immune system health

Maintain/support healthy immune system function

Maintain/support immune system to fight illness

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

Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep

Traditionally used in Chinese medicine to decrease/reduce/relieve bronchial mucous congestion

Traditionally used in Chinese medicine to decrease/reduce/relieve mild upper respiratory tract congestion

Traditionally used in Chinese medicine to antitussive/cough suppressant

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

Indication Requirements

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

Label statement: If symptoms persist, talk to your health professional.

Respiratory tract infections must be qualified by 'mild'.

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 immunological diseases.

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 chronic fatigue syndrome.

Standard Indications

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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 Or.

Visual Identification

Activo	Ingredients
ACLIVE	mgreatents

Cordyceps sinensis hyphae Extract dry concentrate	150 mg
Equivalent: Cordyceps sinensis (Dry)	1.5 g
Ganoderma lucidum fruiting body Extract dry concentrate	150 mg
Equivalent: Ganoderma lucidum (Dry)	1.5 g
Grifola frondosa fruiting body Extract dry concentrate	150 mg
Equivalent: Grifola frondosa (Dry)	1.5 g
Lentinula edodes fruiting body Extract dry concentrate	150 mg
Equivalent: Lentinula edodes (Dry)	1.5 g
Trametes versicolor fruiting body Extract dry concentrate	100 mg
Equivalent: Trametes versicolor (Dry)	1 g
Tremella fuciformis fruiting body Extract dry concentrate	50 mg
Equivalent: Tremella fuciformis (Dry)	500 mg
Wolfiporia cocos fruiting body Extract dry concentrate	50 mg
Equivalent: Wolfiporia cocos (Dry)	500 mg
Other Ingradients (Evaluate)	

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

leucine

medium chain triglycerides

microcrystalline cellulose

potable water

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