



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387757	Bright Mind Complex
ARTG entry for	Medicine Listed	
Sponsor	Ora Health Pty Ltd	
Postal Address	24/10-18 Orchard Road, Brookvale, NSW, 2100 Australia	
ARTG Start Date	2/05/2022	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . Bright Mind Complex

Product Type	Single Medicine Product	Effective Date	2/05/2022
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Permitted Indications

- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Helps enhance/improve/promote/increase attention span
- Traditionally used in Western herbal medicine to decrease/reduce mental/cognitive fatigue
- Maintain/support mental concentration/focus/clarity
- Enhance/improve/promote/increase cognitive performance
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase mental alertness/wakefulness
- Enhance/improve/promote/increase mental alertness/wakefulness
- Enhance/improve/promote/increase memory/recall
- Traditionally used in Western herbal medicine to nerve stimulant/enhance nerve function
- Traditionally used in Ayurvedic medicine to nervine/support nervous system

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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

- Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.
- Adults only.
- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

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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

Alpinia galanga rhizome Extract dry concentrate **150 mg**

Equivalent: Alpinia galanga (Dry) 1.5 g

Bacopa monnieri whole plant Extract dry concentrate standardised **150 mg**

Equivalent: Bacopa monnieri (Dry) 3000 mg

Ilex paraguariensis leaf Extract dry concentrate **250 mg**

Equivalent: Ilex paraguariensis (Dry) 1000 mg

Ocimum tenuiflorum whole plant Extract dry concentrate **80 mg**

Equivalent: Ocimum tenuiflorum (Dry) 800 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

dextrin

hypromellose

leucine

maltodextrin

microcrystalline cellulose

silicon dioxide

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