Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 391741 Sharp Mind

ARTG entry for Medicine Listed

Sponsor myBrainCo.

Postal Address 150 Coburns Road, Melton, VIC, 3337

4/07/2022 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

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 . Sharp Mind

Product Type Effective Date 30/05/2023 Single Medicine Product

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition

Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence

Traditionally used in Western herbal medicine to relieve weariness/firedness/fatigue/feeling of weakness

Traditionally used in Western herbal medicine to body tonic

Helps enhance/promote general health and wellbeing

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

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

Maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to astringent/tightens tissues

Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)

Helps enhance/improve/promote/increase attention span

Decrease/reduce mental/cognitive fatigue

Traditionally used in Western herbal medicine to decrease/reduce mental/cognitive fatigue

Maintain/support mental concentration/focus/clarity

Enhance/improve/promote/increase cognitive performance

Enhance/improve/promote/increase mental endurance/stamina

Enhance/improve/promote/increase mental endurance/stamina

Maintain/support cognitive function/mental function

Maintain/support learning and information processing

Enhance/improve/promote learning ability/function

Enhance/improve/promote/increase mental alertness/wakefulness

Enhance/improve/promote/increase memory/recall

Maintain/support memory/mental recall

Enhance/improve/promote/increase short term memory

Maintain/support brain function

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Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild migraine symptoms

Traditionally used in Ayurvedic medicine to nerve tonic

Traditionally used in Western herbal medicine to nerve tonic

Traditionally used in Western herbal medicine to nerve stimulant/enhance nerve function

Traditionally used in Western herbal medicine to nervine/support nervous system

Traditionally used in Ayurvedic medicine to nervine/support nervous system

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic 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.

Product presentation must not imply or refer to serious cardiovascular conditions.

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

Product presentation must only refer to mild migraine.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

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.

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

acetyl levocarnitine hydrochloride	100 mg
Bacopa monnieri whole plant Extract dry concentrate standardised	150 mg
Equivalent: Bacopa monnieri (Dry)	3000 mg
Cynara scolymus leaf Extract dry concentrate	75 mg
Equivalent: Cynara scolymus (Dry)	1.6875 g
Ginkgo biloba leaf Extract dry concentrate	75 mg
Equivalent: Ginkgo biloba (Dry)	3.75 g
Paullinia cupana seed Extract dry concentrate	71.6 mg
Equivalent: Paullinia cupana (Dry)	716 mg
Plectranthus barbatus root Extract dry concentrate	15 mg
Equivalent: Plectranthus barbatus (Dry)	1.32 g
Rhodiola rosea root Extract dry concentrate	75 mg
Equivalent: Rhodiola rosea (Dry)	600 mg
soy phosphatidylserine-enriched soy lecithin powder	125 mg
Equivalent: soy phosphatidylserine	75 mg

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Other Ingredients (Excipients)

ascorbyl palmitate
colloidal anhydrous silica
hypromellose
magnesium stearate
mixed (low-alpha type) tocopherols concentrate
purified water
silicon dioxide

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