

### **Australian Government**

### **Department of Health**

### Therapeutic Goods Administration

#### **Public Summary**

Summary for ARTG Entry: Super Brahmi 6000 94754

ARTG entry for Medicine Listed

Herbs of Gold Pty Ltd Sponsor

Postal Address PO Box 3143, KIRRAWEE, NSW, 2232

ARTG Start Date 10/06/2003 **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 . Super Brahmi 6000

**Product Type** Effective Date 2/02/2021 Single Medicine Product

## **Permitted Indications**

Antioxidant/Reduce free radicals formed in the body

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

Maintain/support mental concentration/focus/clarity

Traditionally used in Ayurvedic medicine to maintain/support mental concentration/focus/clarity

Enhance/improve/promote/increase cognitive performance in elderly individuals

Enhance/improve/promote/increase cognitive performance in adolescents

Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase cognitive performance

Enhance/improve/promote/increase cognitive performance in teenagers

Maintain/support cognitive function/mental function in children

Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function

Maintain/support cognitive function/mental function in adolescents

Maintain/support cognitive function/mental function in elderly individuals

Maintain/support cognitive function/mental function

Maintain/support cognitive function/mental function in teenagers

Traditionally used in Ayurvedic medicine to enhance/improve/promote learning ability/function

Enhance/improve/promote/increase memory/recall in teenagers

Enhance/improve/promote/increase memory/recall in elderly individuals

Enhance/improve/promote/increase memory/recall in adolescents

Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase memory/recall

Maintain/support memory/mental recall in adolescents

Maintain/support memory/mental recall in teenagers

Maintain/support memory/mental recall in children

Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall

Maintain/support memory/mental recall

Maintain/support memory/mental recall in elderly individuals

Traditionally used in Ayurvedic medicine to brain tonic/Enhance brain health

Traditionally used in Ayurvedic medicine to nervine/support nervous system

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# **Australian Government**

### **Department of Health**

### Therapeutic Goods Administration

### **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.

#### 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 Tablet, film coated

Route of Administration Oral

Visual Identification

**Active Ingredients** 

Bacopa monnieri whole plant Extract dry concentrate standardised

300 mg

Equivalent: Bacopa monnieri (Dry)

6000 mg

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

crospovidone

hypromellose

iron oxide red

macrogol 400

macrogol 8000

magnesium stearate

microcrystalline cellulose

povidone

purified talc

stearic acid

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