Public Summary

Summary for ARTG Entry:	93564 Cerebrum compositum
ARTG entry for	Medicine Listed
Sponsor	Brauer Professional Pty Ltd
Postal Address	PO Box 174, GLEN OSMOND, SA, 5064 Australia
ARTG Start Date	20/03/2003
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'.

Sponsors must confirm the absence of aristolochic acids, in all medicines containing herbal material derived from any of the following plant genera - Akebia, Asarum, Bragantia, Clematis, Cocculus, Diploclisia, Menispermum, Saussurea, Sinomenium, Stephania, Vladimiria.
The confirmation must be undertaken by chemical analysis using Liquid Chromatography Mass Spectrometry (LC-MS). The methodology used should adhere to best practice according to contemporary scientific literature.
Confirmatory evidence is to be provided to the Director of Listing Compliance, Complementary and OTC Medicines Branch, prior to supply of each batch in Australia. The evidence submitted to the TGA is to include the certificate of analysis, all relevant details of the methodology, such as analytical method validation data, and the raw results.
All supporting evidence must be approved by the TGA prior to supply of the batch in Australia.

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Cerebrum compositum

Product Type	Single Medicine Product	**Effective Date**	9/07/2019

Permitted Indications

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

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

Traditionally used in Homoeopathic medicine to maintain/support learning and information processing

Traditionally used in Homoeopathic medicine to enhance/improve/promote/increase mental alertness/wakefulness

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

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Homoeopathic product/preparation or medicine (or words to that effect)

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Contains lactose (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Tablet, uncoated
Route of Administration	Oral
Visual Identification	

Active Ingredients

Aconitum napellus whole plant (Homeopathic)	**1 mg**
Equivalent: Total alkaloids (of Aconitum spp.)	3.2 picogram
Aesculus hippocastanum seed (Homeopathic)	**1 mg**
Anamirta cocculus fruit (Homeopathic)	**1 mg**
Equivalent: Picrotoxin	1.5 ng
Arnica montana root and rhizome (Homeopathic)	**1 mg**
Cinchona pubescens stem bark (Homeopathic)	**1 mg**
Equivalent: quinine	4.5 ng
Equivalent: Quinidine	3 ng
Conium maculatum herb flowering (Homeopathic)	**1 mg**
dibasic magnesium phosphate trihydrate (Homeopathic)	**1 mg**
Gelsemium sempervirens root and rhizome (Homeopathic)	**1 mg**
Hyoscyamus niger whole plant (Homeopathic)	**1 mg**
Equivalent: Hyoscine	.076 picogram
Equivalent: Alkaloids calculated as hyoscyamine	.19 picogram
monobasic potassium phosphate (Homeopathic)	**1 mg**
phosphoric acid (Homeopathic)	**1 mg**
Porcine (Homeopathic)	**1 mg**
Porcine (Homeopathic)	**1 mg**
Porcine (Homeopathic)	**1 mg**
Porcine (Homeopathic)	**1 mg**
potassium dichromate (Homeopathic)	**1 mg**
Ruta graveolens herb flowering (Homeopathic)	**1 mg**
selenium (Homeopathic)	**1 mg**
Semecarpus anacardium fruit (Homeopathic)	**1 mg**
Strychnos ignatii seed (Homeopathic)	**1 mg**
Equivalent: strychnine (of Strychnos spp.)	.36 picogram
sublimed sulfur (Homeopathic)	**1 mg**
Thuja occidentalis shoot top (Homeopathic)	**1 mg**

Other Ingredients (Excipients)

lactose monohydrate

magnesium stearate

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