Public Summary

Summary for ARTG Entry:	345751 Calm Oral Liquid
ARTG entry for	Medicine Listed
Sponsor	Brauer Natural Medicine Pty Ltd
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia
ARTG Start Date	12/10/2020
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.

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 . Calm Oral Liquid

Product Type	Single Medicine Product	**Effective Date**	29/07/2022

Permitted Indications

Traditionally used in Homoeopathic medicine to relieve irritability
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of stress
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms
Traditionally used in Homoeopathic medicine to enhance/promote/increase refreshing sleep
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep

Indication Requirements

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

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)

(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 sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

Anamirta cocculus fruit (Homeopathic)	**5 nanolitre/mL**
Equivalent: Picrotoxin	70 picogram/mL
Chamaelirium luteum root and rhizome (Homeopathic)	**5 nanolitre/mL**
Passiflora incarnata herb flowering (Homeopathic)	**5 microlitre/mL**
phosphoric acid (Homeopathic)	**60 nanolitre/mL**
sepia (Homeopathic)	**50 nanolitre/mL**
Strychnos ignatii seed (Homeopathic)	**50 microlitre/mL**
Equivalent: strychnine (of Strychnos spp.)	8.5 ng/mL
Strychnos nux-vomica seed (Homeopathic)	**1.67 microlitre/mL**
Equivalent: strychnine (of Strychnos spp.)	0 picogram/mL
zinc (Homeopathic)	**50 nanolitre/mL**

Other Ingredients (Excipients)

ascorbic acid
ethanol
Flavour
potassium sorbate
purified water
Rosa canina
sucrose

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