



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	350163	Sleep Oral Spray
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	30/11/2020	
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'.

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 . Sleep Oral Spray

Product Type	Single Medicine Product	Effective Date	30/11/2020
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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 symptoms of mild anxiety
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mental overactivity
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 only refer to mild anxiety.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
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)

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

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Dosage Form Spray, solution

Route of Administration Sublingual

Visual Identification

Active Ingredients

Capsicum annuum fruit (Homeopathic)	111.111 microlitre/mL
Coffea arabica seed (Homeopathic)	111.111 microlitre/mL
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Gelsemium sempervirens root and rhizome (Homeopathic)	111.111 microlitre/mL
Humulus lupulus fruit (Homeopathic)	111.111 microlitre/mL
Hyoscyamus niger whole plant (Homeopathic)	111.111 microlitre/mL
Equivalent: Alkaloids calculated as hyoscyamine	0 microlitre/mL
Equivalent: Hyoscine	0 microlitre/mL
Matricaria chamomilla whole plant (Homeopathic)	111.111 microlitre/mL
Passiflora incarnata herb flowering (Homeopathic)	111.111 microlitre/mL
Valeriana officinalis root and rhizome and stolon (Homeopathic)	111.111 microlitre/mL

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