Public Summary

Summary for ARTG Entry:	338769 Neurexan
ARTG entry for	Medicine Listed
Sponsor	Bio-Practica Pty Ltd
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia
ARTG Start Date	2/07/2020
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.

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.

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 . Neurexan

Product Type Single Medicine Product **Effective Date** 2/07/2020

Permitted Indications

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 maintains/supports refreshing sleep
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep
Traditionally used in Homoeopathic medicine to enhance/promote/increase healthy sleep patterns
Traditionally used in Homoeopathic medicine to maintain/support healthy sleeping patterns

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains lactose (or words to that effect).
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].

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

Avena sativa herb flowering (Homeopathic)	**600 microgram**
Coffea arabica seed (Homeopathic)	**600 microgram**
Passiflora incarnata herb flowering (Homeopathic)	**600 microgram**
zinc valerate (Homeopathic)	**600 microgram**
Equivalent: zinc	129.2 ng

Other Ingredients (Excipients)

lactose monohydrate

magnesium stearate

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