



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		470151	AnxioEase
ARTG entry for	Medicine Listed		
Sponsor	Biomedica Nutraceuticals Pty Ltd		
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia		
ARTG Start Date	25/11/2024		
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 . AnxioEase

Product Type	Single Medicine Product	Effective Date	25/11/2024
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Permitted Indications

Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
Traditionally used in Chinese medicine to antispasmodic/spasmolytic
Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
Traditionally used in Chinese medicine to decrease/reduce/relieve muscle tension/stiffness
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Traditionally used in Ayurvedic medicine to enhance/promote body adaptation to stress
Support healthy stress response in the body
Traditionally used in Chinese medicine to support healthy stress response in the body
Traditionally used in Chinese medicine to relieve irritability
Traditionally used in Western herbal medicine to relieve irritability
Traditionally used in Chinese medicine to calms the mind
Traditionally used in Western herbal medicine to soothe/calm nerves
Traditionally used in Chinese medicine to soothe/calm nerves
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of stress
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
Decrease/reduce/relieve symptoms of stress
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Chinese medicine to decrease/reduce/relieve headache symptoms
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Traditionally used in Western herbal medicine to nervine/support nervous system
Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep



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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.

Product presentation must only refer to mild anxiety.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Magnolia officinalis stem bark Extract dry concentrate	225 mg
Equivalent: Magnolia officinalis (Dry)	1.125 g
Ocimum tenuiflorum herb top Extract dry concentrate	62.5 mg
Equivalent: Ocimum tenuiflorum (Dry)	1.25 g
Passiflora incarnata herb top Extract dry concentrate	48.75 mg
Equivalent: Passiflora incarnata (Dry)	975 mg
Pueraria lobata root Extract dry concentrate	120 mg
Equivalent: Pueraria lobata (Dry)	3 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	125 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	2.25 g

Other Ingredients (Excipients)

carrageenan
colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
potassium acetate
purified water
silicon dioxide