



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375453	Anxioton
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	29/09/2021	
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 . Anxioton

Product Type	Single Medicine Product	Effective Date	29/09/2021
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Permitted Indications

Maintain/support general health and wellbeing

Traditionally used in Pacific Islander medicine to decrease/reduce/relieve mild joint aches and pains

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative

Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

Traditionally used in Western herbal medicine to relieve digestive discomfort

Traditionally used in Pacific Islander medicine to maintain/support muscle relaxation

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress

Traditionally used in Pacific Islander medicine to decrease/reduce/relieve symptoms of stress

Linked indication - Decrease/reduce/relieve disturbed/restless sleep

Linked indication - Maintain/support healthy sleeping patterns

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety

Traditionally used in Pacific Islander medicine to decrease/reduce/relieve symptoms of mild anxiety

Maintain/support nervous system health

Traditionally used in Pacific Islander medicine to maintain/support nervous system health

Traditionally used in Western herbal medicine to calmative/nervous system relaxant

Traditionally used in Pacific Islander medicine to calmative/nervous system relaxant

Traditionally used in Pacific Islander medicine to nerve/support nervous system

Traditionally used in Western herbal medicine to nerve/support nervous system

Maintain/support nervous system function

Traditionally used in Western herbal medicine to decrease/reduce/relieve mild nerve pain/neuralgia

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Pacific Islander medicine to decrease/reduce/relieve disturbed/restless sleep

Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns

Traditionally used in Pacific Islander medicine to aid/assist flushing of the urinary tract



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Indication Requirements

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

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

Product presentation must only refer to mild anxiety.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must only refer to mild nerve pain/neuralgia.

Product presentation must only refer to mild joint symptoms.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Not for prolonged use. If symptoms persist, seek advice from a health care practitioner. Not recommended for use by pregnant or lactating women (or words to that effect). May harm the liver.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

glycine	100 mg
magnesium amino acid chelate	250 mg
Equivalent: magnesium	50 mg
Magnolia officinalis stem bark Extract dry concentrate	150 mg
Equivalent: Magnolia officinalis (Dry)	1.5 g
Melissa officinalis flower and leaf Extract dry concentrate	75 mg
Equivalent: Melissa officinalis (Dry)	750 mg
Passiflora incarnata herb top flowering Extract dry concentrate	75 mg
Equivalent: Passiflora incarnata (Dry)	1.5 g
Piper methysticum root Extract dry concentrate standardised	400 mg
Equivalent: Piper methysticum (Dry)	3.2 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	300 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	3 g

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

Carnauba Wax

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colloidal anhydrous silica
crospovidone
hypromellose
macrogol 8000
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
purified water

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