



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	375453	Anxioton
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	29/09/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 Pacific Islander medicine to decrease/reduce/relieve symptoms of stress  
Linked indication - Maintain/support healthy sleeping patterns  
Linked indication - Decrease/reduce/relieve disturbed/restless sleep  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress  
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 nervine/support nervous system  
Traditionally used in Western herbal medicine to nervine/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 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 not imply or refer to gastro oesophageal reflux disease.

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

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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