



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	394791	MagCalm
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	26/08/2022	
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 . MagCalm

Product Type	Single Medicine Product	Effective Date	26/08/2022
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Permitted Indications

Maintain/support natural liver cleansing/detoxification processes
Maintain/support general health and wellbeing
Maintain/support cardiovascular system health
Helps maintain/support healthy heart function
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support bile production
Maintain/support healthy neuromuscular system/function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral) within normal range
Traditionally used in Western herbal medicine to soothe/calm nerves
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
Maintain/support neuromuscular function
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
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
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 not imply or refer to drugs/alcohol.
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
Product presentation must not imply or refer to serious cardiovascular conditions.



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Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

If product is indicated for supplementation, 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 only refer to mild anxiety.

Product presentation must only refer to detoxification in relation to natural body processes.

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 only refer to mild nerve pain/neuralgia.

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 Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

glycine	190.48 mg/g
magnesium glycinate dihydrate	250.63 mg/g
Equivalent: magnesium	28.57 mg/g
Melissa officinalis leaf Extract dry concentrate	28.57 mg/g
Equivalent: Melissa officinalis (Dry)	285.71 mg/g
Passiflora incarnata herb Extract dry concentrate	14.29 mg/g
Equivalent: Passiflora incarnata (Dry)	285.71 mg/g
taurine	285.71 mg/g

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

sodium bicarbonate

Stevia rebaudiana

Public Summary

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