



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	343214	Mg Optima Relax
ARTG entry for	Medicine Listed	
Sponsor	Natural Bio Pty Limited	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	9/09/2020	
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.

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 . Mg Optima Relax

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

- Decrease/reduce/relieve muscle cramps
- Maintain/support healthy muscle contraction function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Aid/assist/helps mind relaxation
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety
- Helps reduce occurrence of symptoms of mild anxiety
- Maintain/support mental concentration/focus/clarity
- Maintain/support cognitive function/mental function
- Decrease/reduce/relieve headache symptoms
- Decrease/reduce/relieve mild migraine symptoms
- Helps reduce occurrence of mild migraines
- Decrease/reduce duration of mild migraine
- Aid/assist/helps synthesis of neurotransmitters
- Enhance/improve/promote/increase sleep quality/deep sleep

Indication Requirements

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

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 only refer to mild migraine.

Product presentation must only refer to mild anxiety.

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

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.
Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Adults only.

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

Camellia sinensis leaf Extract dry concentrate standardised	100 mg/g
Equivalent: caffeine ()	3 mg/g
glutamine	100 mg/g
magnesium glycinate	225 mg/g
Equivalent: magnesium	30 mg/g
pyridoxal 5-phosphate monohydrate	3.12 mg/g
Equivalent: pyridoxine	2 mg/g
zinc citrate dihydrate	3.116 mg/g
Equivalent: zinc	1 mg/g

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

malic acid

maltodextrin

Stevia rebaudiana

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