



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	19/07/2023
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### Permitted Indications

Maintain/support general health and wellbeing  
Decrease/reduce/relieve muscle cramps when dietary intake is inadequate  
Maintain/support healthy muscle contraction function  
Maintain/support muscle health  
Maintain/support muscle function  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Aids/assists the body to cope with environmental stress  
Support healthy stress response in the body  
Aid/assist/helps mind relaxation  
Decrease/reduce/relieve nervous tension/unrest when dietary intake is inadequate  
Maintain/support mental concentration/focus/clarity  
Maintain/support cognitive function/mental function  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system function  
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.

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 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

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### Warnings

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.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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.

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

### 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

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

#### Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

Flavour

malic acid

maltodextrin

Stevia rebaudiana

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