



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

## Public Summary

<b>Summary for ARTG Entry:</b>	333212	Calm Mind
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	I'm Nutrients	
<b>Postal Address</b>	4E Wentworth Street, Point Piper, NSW, 2027 Australia	
<b>ARTG Start Date</b>	2/04/2020	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Calm Mind

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/04/2020
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### Permitted Indications

Maintain/support energy production  
Maintain/support healthy growth and development in children  
Maintain/support healthy growth and development  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle function  
Maintain/support muscle relaxation  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Relieve irritability in children over 12 years of age  
Relieve irritability  
Calms the mind  
Calms the mind in children over 12 years of age  
Help maintain/support emotional wellbeing in children over 12 years of age  
Help maintain/support emotional wellbeing  
Soothe/calm nerves  
Soothe/calm nerves  
Soothe/calm nerves in children over 12 years of age  
Decrease/reduce/relieve symptoms of stress  
Decrease/reduce/relieve nervous tension/unrest  
Decrease/reduce/relieve nervous tension/unrest in children over 12 years of age  
Decrease/reduce/relieve symptoms of mild anxiety in children over 12 years of age  
Decrease/reduce/relieve symptoms of mild anxiety  
Maintain/support brain function

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Aid/assist/helps synthesis of neurotransmitters  
 Maintain/support nervous system health  
 Maintain/support nervous system function  
 Maintain/support wound healing

**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.  
 Product presentation must only refer to mild anxiety.  
 Product presentation must not imply or refer to serious immunological diseases.  
 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).  
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

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

**Visual Identification**

**Active Ingredients**

<b>calcium folinate</b>	<b>54.3 microgram</b>
Equivalent: folic acid	50 microgram
<b>Crocus sativus stigma Extract dry concentrate</b>	<b>10 mg</b>
Equivalent: Crocus sativus (Dry)	30 mg
<b>magnesium citrate</b>	<b>432.1 mg</b>
Equivalent: magnesium	70 mg
<b>mecobalamin (co-methylcobalamin)</b>	<b>50 microgram</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>10.66 mg</b>
Equivalent: pyridoxine	6.8 mg
<b>zinc citrate</b>	<b>18.69 mg</b>
Equivalent: zinc	6 mg

**Other Ingredients (Excipients)**

beetroot  
 citric acid  
 colloidal anhydrous silica  
 Flavour  
 isomalt  
 magnesium stearate  
 rice starch  
 Siraitia grosvenorii

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**thaumatin**

**xylitol**

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