



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

## Public Summary

<b>Summary for ARTG Entry:</b>	337129	ETHICAL NUTRIENTS MEGA MAGNESIUM ENERGY & STRESS
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	27/05/2020	
<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 . ETHICAL NUTRIENTS MEGA MAGNESIUM ENERGY & STRESS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/05/2020
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### Permitted Indications

- Maintain/support energy levels
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Maintain/support general health and wellbeing
- Maintain/support healthy thyroid hormones
- Aid/assist thyroid hormone production
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Support healthy stress response in the body when dietary intake is inadequate
- Support healthy stress response in the body
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress when dietary intake is inadequate
- Decrease/reduce mental/cognitive fatigue

### Indication Requirements

- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Label statement: If symptoms persist, talk to your health professional.
- 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 any thyroid related diseases.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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#### Warnings

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

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

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.

#### Additional Product information

#### Pack Size/Poison information

##### Pack Size

##### Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form** Powder

**Route of Administration** Oral

##### Visual Identification

#### Active Ingredients

<b>acetyl levocarnitine hydrochloride</b>	<b>167.86 mg/g</b>
<b>ascorbic acid</b>	<b>5.43 mg/g</b>
<b>calcium pantothenate</b>	<b>7.14 mg/g</b>
<b>magnesium amino acid chelate</b>	<b>428.57 mg/g</b>
Equivalent: magnesium	42.86 mg/g
<b>nicotinamide</b>	<b>7.14 mg/g</b>
<b>potassium iodide</b>	<b>14.01 microgram/g</b>
Equivalent: iodine	10.65 microgram/g
<b>pyridoxine hydrochloride</b>	<b>3.57 mg/g</b>
Equivalent: pyridoxine	2.94 mg/g
<b>Rhodiola rosea root Extract dry concentrate</b>	<b>17.86 mg/g</b>
Equivalent: Rhodiola rosea (Dry)	71.43 mg/g
<b>riboflavin</b>	<b>3.57 mg/g</b>
<b>selenomethionine</b>	<b>17.86 microgram/g</b>
Equivalent: selenium	7.14 microgram/g
<b>thiamine hydrochloride</b>	<b>5.43 mg/g</b>
<b>zinc amino acid chelate</b>	<b>7.14 mg/g</b>
Equivalent: zinc	1.43 mg/g

#### Other Ingredients (Excipients)

**calcium hydrogen phosphate**

**citric acid**

**Flavour**

**malic acid**

**maltodextrin**

**silicon dioxide**

**Steviol glycosides**

Public Summary

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