



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

## Public Summary

<b>Summary for ARTG Entry:</b>	376951	ETHICAL NUTRIENTS MEGA MAGNESIUM NIGHT TABLETS
<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>	27/10/2021	
<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 . ETHICAL NUTRIENTS MEGA MAGNESIUM NIGHT TABLETS

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/10/2021
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#### Permitted Indications

Maintain/support healthy muscle contraction function  
Maintain/support muscle function  
Maintain/support muscle relaxation  
Support healthy stress response in the body  
Traditionally used in Western herbal medicine to calms the mind  
Calms the mind  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress  
Linked indication - Decrease/reduce/relieve disturbed/restless sleep  
Maintain/support nervous system function  
Maintain/support healthy sleeping patterns

#### 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.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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

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

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>magnesium amino acid chelate</b>	<b>575 mg</b>
Equivalent: magnesium	115 mg
<b>magnesium glycinate dihydrate</b>	<b>350 mg</b>
Equivalent: magnesium	35 mg
<b>Passiflora incarnata herb Extract dry concentrate</b>	<b>273 mg</b>
Equivalent: Passiflora incarnata (Dry)	1.5 g

**Other Ingredients (Excipients)**

**Carnauba Wax**

**citric acid**

**croscarmellose sodium**

**hypromellose**

**macrogol 400**

**magnesium stearate**

**microcrystalline cellulose**

**silicon dioxide**

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