



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

## Public Summary

<b>Summary for ARTG Entry:</b>	323768	Magnesium Night Plus
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	18/09/2019	
<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 . Magnesium Night Plus

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	10/02/2022
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### Permitted Indications

- Maintain/support energy production
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Maintain/support bone health
- Maintain/support cardiovascular system health
- Maintain/support heart health
- Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
- Helps reduce occurrence of muscle cramp when dietary intake is inadequate
- Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
- Maintain/support healthy muscle contraction function
- Maintain/support muscle health
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Support healthy stress response in the body
- Traditionally used in Western herbal medicine to calms the mind
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support nervous system health
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant
- Maintain/support nervous system function
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Traditionally used in Western herbal medicine to enhance/promote/increase refreshing sleep
- Traditionally used in Western herbal medicine to maintains/supports refreshing sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep

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**Indication Requirements**

Label statement: If symptoms persist, talk to your health professional.

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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 mental illnesses, disorders or conditions.

Product presentation must only refer to mild anxiety.

Product presentation must not imply or refer to serious cardiovascular conditions.

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.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

**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.

**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>calcium citrate tetrahydrate</b>	<b>78.989 mg/g</b>
Equivalent: calcium	16.667 mg/g
<b>Eschscholzia californica herb Extract dry concentrate</b>	<b>41.667 mg/g</b>
Equivalent: Eschscholzia californica (Dry)	250.002 mg/g
<b>glutamine</b>	<b>83.333 mg/g</b>
<b>magnesium citrate</b>	<b>133 mg/g</b>
Equivalent: magnesium	20 mg/g
<b>magnesium glycinate dihydrate</b>	<b>296.666 mg/g</b>
Equivalent: magnesium	33.333 mg/g
<b>Passiflora incarnata herb Extract dry concentrate</b>	<b>15.151 mg/g</b>
Equivalent: Passiflora incarnata (Dry)	83.331 mg/g

**Other Ingredients (Excipients)**

**Acacia**

**citric acid**

**colloidal anhydrous silica**

**Flavour**

**malic acid**

**maltodextrin**

**Stevia rebaudiana**

**thaumatin**



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