



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	323768	Magnesium Night Plus
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	18/09/2019	
Product Category	Medicine	
Status	Active	
Approval Area	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

Product Type	Single Medicine Product	Effective Date	19/07/2023
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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

Product presentation must only refer to mild anxiety.

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.

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

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.

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

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

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

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