



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

## Public Summary

<b>Summary for ARTG Entry:</b>	392710	Tri-Mag Restful Night Chocolate
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Designs For Health Pty Ltd	
<b>Postal Address</b>	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
<b>ARTG Start Date</b>	25/07/2022	
<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 . Tri-Mag Restful Night Chocolate

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/07/2022
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### Permitted Indications

Maintain/support energy production  
Maintain/support body electrolyte balance  
Maintain/support general health and wellbeing  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
Maintain/support bone mass/density/integrity  
Helps maintain/support healthy blood sugar/glucose  
Maintain/support cardiovascular system health  
Helps maintain/support healthy heart function  
Maintain/support heart health  
Maintain/support healthy muscle contraction function  
Maintain/support muscle health  
Maintain/support muscle function  
Maintain/support healthy neuromuscular system/function  
Maintain/support muscle relaxation  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Aid/assist/helps protein synthesis in the body  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Help maintain/support emotional wellbeing  
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy  
Maintain/support nerve conduction  
Maintain/support nervous system health  
Maintain/support nervous system function  
Support healthy emotional/mood balance  
Traditionally used in Western herbal medicine to soporific/induces sleep

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Enhance/promote/increase refreshing sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Enhance/improve/promote/increase sleep quality/deep sleep

#### Indication Requirements

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

Product presentation must not imply or refer to mental illnesses, disorders or 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.

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

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

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

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 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).

#### 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

Pack Size

Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form** Powder

**Route of Administration** Oral

#### Visual Identification

#### Active Ingredients

<b>Crocus sativus stigma Dry</b>	<b>3.6 mg/g</b>
Equivalent: Crocus sativus (Dry)	12 mg/g
<b>Eschscholzia californica herb top flowering Extract dry concentrate</b>	<b>14.29 mg/g</b>
Equivalent: Eschscholzia californica (Dry)	214.29 mg/g
<b>glycine</b>	<b>428.57 mg/g</b>
<b>magnesium citrate</b>	<b>44.18 mg/g</b>
Equivalent: magnesium	7.14 mg/g
<b>magnesium glycerophosphate</b>	<b>129.91 mg/g</b>
Equivalent: magnesium	14.29 mg/g
<b>magnesium glycinate</b>	<b>151.98 mg/g</b>
Equivalent: magnesium	21.43 mg/g
<b>Passiflora incarnata herb flowering Extract dry concentrate</b>	<b>4.2857 mg/g</b>
Equivalent: Passiflora incarnata (Dry)	428.57 mg/g

#### Other Ingredients (Excipients)

Acacia

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citric acid dihydrate  
colloidal anhydrous silica  
dextrin  
Flavour  
maltodextrin  
Stevia rebaudiana

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