



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	288875	MediHerb MediMag Calm
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	12/05/2017	
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 . MediHerb MediMag Calm

Product Type	Single Medicine Product	Effective Date	25/03/2021
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Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to balance Vata
- Traditionally used in Ayurvedic medicine to balance aggravated Vata
- Traditionally used in Ayurvedic medicine to enhance/promote energy levels
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence In older males
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence in healthy elderly individuals
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence In older females
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility In older males
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility In older females
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility in healthy elderly individuals
- Traditionally used in Ayurvedic medicine to longevity tonic
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in teenagers
- Maintain/support general health and wellbeing in healthy adolescents
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in healthy children
- Maintain/support healthy muscle contraction function
- Maintain/support muscle health
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support muscle relaxation
- Maintain/support muscle tone
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy adolescents
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy children



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Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Maintain/support (state vitamin/mineral) within normal range in children
Maintain/support (state vitamin/mineral) within normal range in healthy adolescents
Maintain/support (state vitamin/mineral) within normal range in teenagers
Maintain/support (state vitamin/mineral) within normal range in healthy children
Maintain/support (state vitamin/mineral) within normal range
Support healthy stress response in the body
Traditionally used in Ayurvedic medicine to calms the mind
Traditionally used in Ayurvedic medicine to soothe/calm nerves
Traditionally used in Ayurvedic medicine to enhance/improve/promote learning ability/function
Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase memory/recall
Traditionally used in Ayurvedic medicine to nerve tonic
Traditionally used in Ayurvedic medicine to nerve tonic
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Traditionally used in Ayurvedic medicine to calmative/nervous system relaxant
Traditionally used in Ayurvedic medicine to soporific/induces sleep
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness
Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to chronic fatigue syndrome.

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).

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

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder, oral
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Route of Administration	Oral
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Visual Identification



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Active Ingredients

ascorbic acid	20.83 mg/g
calcium pantothenate	4.17 mg/g
Equivalent: calcium	349.86 microgram/g
Equivalent: pantothenic acid	3.82 mg/g
dibasic potassium phosphate	18.56 mg/g
Equivalent: potassium	8.33 mg/g
glutamine	125 mg/g
glycine	125 mg/g
magnesium citrate	154.7 mg/g
Equivalent: magnesium	25 mg/g
pyridoxal 5-phosphate monohydrate	6.53 mg/g
Equivalent: pyridoxine	4.17 mg/g
taurine	125 mg/g
Withania somnifera root Extract dry concentrate standardised	12.5 mg/g
Equivalent: Withania somnifera (Dry)	125 mg/g
zinc citrate dihydrate	3.89 mg/g
Equivalent: zinc	1.25 mg/g

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Flavour
glycine
maltodextrin
Stevia rebaudiana
thaumatin

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