



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	217024	METAGENICS MYOPLEX
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	8/11/2013	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . METAGENICS MYOPLEX

Product Type	Effective Date
Single Medicine Product	6/02/2020

Permitted Indications

- Decrease/reduce/relieve muscle cramps
- Helps decrease/reduce/relieve leg cramps
- Traditionally used in Western herbal medicine to antispasmodic/spasmodic
- Helps decrease/reduce/relieve mild muscle spasms/twitches
- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Traditionally used in Western herbal medicine to relieve irritability
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Decrease/reduce/relieve symptoms of stress
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support nerve conduction
- Maintain/support nervous system health
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant

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Maintain/support nervous system function
 Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

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.
 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 serious musculoskeletal or neurological conditions.

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

calcium lactate	138.9 mg
Equivalent: calcium	25 mg
magnesium amino acid chelate	250 mg
Equivalent: magnesium	50 mg
Passiflora incarnata herb Extract dry concentrate	24.3 mg
Equivalent: Passiflora incarnata (Dry)	133.65 mg
Valeriana officinalis root Extract dry concentrate	12.5 mg
Equivalent: Valeriana officinalis (Dry)	50 mg

Other Ingredients (Excipients)

- Acacia
- alginic acid
- carrageenan
- colloidal anhydrous silica
- croscarmellose sodium
- Guar Gum
- hypromellose
- macrogol 400
- macrogol 8000
- magnesium stearate
- microcrystalline cellulose
- sorbitol

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