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

Permitted Indications

Decrease/reduce/relieve muscle cramps
Helps decrease/reduce/relieve leg cramps
Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
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

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 serious musculoskeletal or neurological conditions.

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

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).

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

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
hyprolose
macrogol 400
macrogol 8000
magnesium stearate
microcrystalline cellulose
sorbitol

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