Public Summary

Summary for ARTG Entry:	340870 PM+ Sleep + Calm Mind
ARTG entry for	Medicine Listed
Sponsor	JSHealth Vitamins Pty Ltd
Postal Address	14/409 New South Head Road, Double Bay, Sydney, NSW, 2028 Australia
ARTG Start Date	5/08/2020
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 . PM+ Sleep + Calm Mind

Product Type Single Medicine Product **Effective Date** 15/03/2022

Permitted Indications

Maintain/support energy production
Maintain/support bone health
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support healthy muscle contraction function
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Maintain/support muscle relaxation
Relieve irritability
Calms the mind
Aid/assist/helps mind relaxation
Soothe/calm nerves
Decrease/reduce/relieve nervous tension/unrest
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support nervous system health
Maintain/support nervous system function
Decrease/reduce/relieve disturbed/restless sleep

Indication Requirements

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

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.

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 only refer to mild anxiety.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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

Lavender Oil	**81 mg**
magnesium amino acid chelate	**100 mg**
Equivalent: magnesium	20 mg
magnesium citrate	**507.52 mg**
Equivalent: magnesium	81 mg
magnesium glycinate	**359.2 mg**
Equivalent: magnesium	50 mg
Matricaria chamomilla flower Extract dry concentrate	**25 mg**
Equivalent: Matricaria chamomilla (Dry)	250 mg
Passiflora incarnata flower Extract dry concentrate	**250 mg**
Equivalent: Passiflora incarnata (Dry)	1.25 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone

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