

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 386812 MediHerb MediMag Sleep

ARTG entry for Medicine Listed

Sponsor Integria Healthcare Australia Pty Ltd

Postal Address PO Box 4854, EIGHT MILE PLAINS, QLD, 4113

7/04/2022 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

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 Sleep

Product Type Effective Date 7/04/2022 Single Medicine Product

Permitted Indications

Maintain/support general health and wellbeing

Traditionally used in Western herbal medicine to antispasmodic/spasmolytic

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

Traditionally used in Western herbal medicine to relieve irritability

Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy

Traditionally used in Western herbal medicine to soothe/calm nerves

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress

Maintain/support nerve conduction

Traditionally used in Western herbal medicine to soporific/induces sleep

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

Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns

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 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

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Warnings

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. For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormPowderRoute of AdministrationOral

Visual Identification

Active Ingredients

glycine 300 mg/g
magnesium citrate 191.83 mg/g
Equivalent: magnesium 31 mg/g

Melissa officinalis herb Extract dry concentrate 11.54 mg/g
Equivalent: Melissa officinalis (Dry) 75 mg/g

Ziziphus jujuba var. spinosa seed Extract dry concentrate 15 mg/g
Equivalent: Ziziphus jujuba var. spinosa (Dry) 150 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

malic acid

maltodextrin Stevia rebaudiana

thaumatin

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