



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	337547	Somnicalm
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	6/06/2020	
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 . Somnicalm

Product Type	Single Medicine Product	Effective Date	3/11/2023
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Traditionally used in Western herbal medicine to antispasmodic/spasmolytic
Traditionally used in Western herbal medicine to maintain/support muscle relaxation
Traditionally used in Chinese medicine to relieve irritability
Traditionally used in Western herbal medicine to relieve irritability
Traditionally used in Chinese medicine to calms the mind
Traditionally used in Chinese medicine to aid/assist/helps mind relaxation
Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Western herbal medicine to nervine/support nervous system
Traditionally used in Chinese medicine to soporific/induces sleep
Traditionally used in Western herbal medicine to soporific/induces sleep
Traditionally used in Western herbal medicine to enhance/promote/increase refreshing sleep
Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep
Traditionally used in Chinese medicine to decrease/reduce time to fall asleep
Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep

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.

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

Product presentation must only refer to mild anxiety.

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



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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

Albizia julibrissin stem bark Extract dry concentrate	40 mg
Equivalent: Albizia julibrissin (Dry)	200 mg
Biota orientalis seed Extract dry concentrate	40 mg
Equivalent: Biota orientalis (Dry)	200 mg
Passiflora incarnata herb Extract dry concentrate	100 mg
Equivalent: Passiflora incarnata (Dry)	500 mg
Polygala tenuifolia root Extract dry concentrate	40 mg
Equivalent: Polygala tenuifolia (Dry)	200 mg
Schisandra chinensis fruit Extract dry concentrate	30 mg
Equivalent: Schisandra chinensis (Dry)	150 mg
Wolfiporia cocos mushroom Extract dry concentrate	40 mg
Equivalent: Wolfiporia cocos (Dry)	200 mg
Ziziphus jujuba var. spinosa seed Extract dry concentrate	250 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	2.5 g

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.