Australian Government

Department of Health

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.

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.

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 . Somnicalm

Product Type Single Medicine Product **Effective Date** 6/06/2020

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 Western herbal medicine to relieve irritability

Traditionally used in Chinese 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 Western herbal medicine to soporific/induces sleep

Traditionally used in Chinese medicine to soporific/induces sleep

Traditionally used in Western herbal medicine to enhance/promote/increase refreshing sleep

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

Traditionally used in Chinese 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

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

Label statement: If symptoms persist, talk to your health professional.

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.

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

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