



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	283014	RejuvaCALM Forte
ARTG entry for	Medicine Listed	
Sponsor	Bio-Practica Pty Ltd	
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	29/11/2016	
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 . RejuvaCALM Forte

Product Type	Single Medicine Product	Effective Date	25/07/2019
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Permitted Indications

- Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating in/of Yin deficiency pattern
- Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
- Helps enhance/promote general health and wellbeing
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of nervous indigestion
- Traditionally used in Western herbal medicine to support healthy stress response in the body
- Traditionally used in Western herbal medicine to relieve irritability
- Traditionally used in Western herbal medicine to aid/assist/helps mind relaxation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase body relaxation
- 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 stress
- Traditionally used in Western herbal medicine to help reduce occurrence of irritability
- Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild nerve pain/neuralgia
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep

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Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep
 Traditionally used in Western herbal 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.
 Product presentation must not imply or refer to gastro oesophageal reflux disease.
 Product presentation must only refer to mild nerve pain/neuralgia.

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
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Lavandula angustifolia	125 mg
Equivalent: Lavandula angustifolia	500 mg
Equivalent: camphor	15.625 mg
Magnolia officinalis	150 mg
Equivalent: Magnolia officinalis	1.5 g
Melissa officinalis	100 mg
Equivalent: Melissa officinalis	1 g
Passiflora incarnata	75 mg
Equivalent: Passiflora incarnata	1.5 g
Ziziphus jujuba var. spinosa	300 mg
Equivalent: Ziziphus jujuba var. spinosa	3 g

Other Ingredients (Excipients)

colloidal anhydrous silica
 disodium edetate
 gellan gum
 hypromellose
 maltodextrin
 microcrystalline cellulose
 potable water
 potassium acetate
 stearic acid

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