



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	343239	RejuvaSleep Forte N
ARTG entry for	Medicine Listed	
Sponsor	Bio-Practica Pty Ltd	
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	10/09/2020	
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 . RejuvaSleep Forte N

Product Type	Single Medicine Product	Effective Date	5/11/2020
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Permitted Indications

Traditionally used in Chinese medicine to decrease/reduce/relieve excessive perspiration/sweating
Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
Maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
Traditionally used in Western herbal medicine to calms the mind
Traditionally used in Western herbal medicine to enhance/improve/promote/increase mind relaxation
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 Chinese medicine to helps reduce occurrence of irritability
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Western herbal medicine to helps reduce occurrence of symptoms of mild anxiety
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Traditionally used in Western herbal medicine to nervine/support nervous system
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 Chinese medicine to decrease/reduce time to fall asleep
Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep
Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep



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

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.

Product presentation must only refer to mild anxiety.

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

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Eschscholzia californica herb Extract dry concentrate	166.67 mg
Equivalent: Eschscholzia californica (Dry)	1000 mg
Lavender Oil	40 mg
Medicago sativa leaf Extract dry concentrate	42 mg
Equivalent: Medicago sativa (Fresh)	3.78 g
Passiflora incarnata herb top flowering Extract dry concentrate	90 mg
Equivalent: Passiflora incarnata (Dry)	1.8 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	250 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
Chlorella vulgaris
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
Oryza sativa
povidone
pregelatinised rice starch