



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	366873	Sleep Complex
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	24/05/2021	
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 . Sleep Complex

Product Type	Single Medicine Product	Effective Date	24/05/2021
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Permitted Indications

Traditionally used in Chinese medicine to decrease/reduce/relieve spontaneous sweating
Traditionally used in Chinese medicine to calms the mind
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Chinese medicine to soporific/induces sleep
Traditionally used in Western herbal medicine to enhance/promote/increase refreshing sleep
Decrease/reduce/relieve sleeplessness
Decrease/reduce time to fall asleep
Decrease/reduce/relieve disturbed/restless sleep
Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep 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.

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
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Components



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1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Lavandula angustifolia flower Oil essential	2 mg
Valeriana officinalis root Extract dry concentrate standardised	375 mg
Equivalent: Valeriana officinalis (Dry)	1.5 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	450 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	4.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
triacetin

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