



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	366873	Sleep Complex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	24/05/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	24/05/2021
---------------------	-------------------------	-----------------------	------------

#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

#### Components



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

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

© 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>.

Public Summary