



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	428001	ProbioCalm
ARTG entry for	Medicine Listed	
Sponsor	Designs For Health Pty Ltd	
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
ARTG Start Date	16/11/2023	
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 . ProbioCalm

Product Type	Single Medicine Product	Effective Date	3/04/2024
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Permitted Indications

Support healthy stress response in the body

Calms the mind

Help maintain/support emotional wellbeing

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress

Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest

Maintain/support general mental wellbeing

Maintain/support nervous system health

Support healthy emotional/mood balance

Traditionally used in Western herbal medicine to soporific/induces 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.

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).

For practitioner dispensing only.

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		
Bifidobacterium longum		2 billion CFU
Crocus sativus stigma Extract dry concentrate		28 mg
Equivalent: Crocus sativus (Dry)		84 mg
Melissa officinalis leaf Extract dry concentrate		300 mg
Equivalent: Melissa officinalis (Dry)		3 g
Other Ingredients (Excipients)		
colloidal anhydrous silica		
dextrin		
hypromellose		
magnesium stearate		
maltodextrin		
microcrystalline cellulose		
purified water		

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