



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	313928	CalmFactors for Juniors
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Level 4 / 64 Kippax Street, Surry Hills, NSW, 2010 Australia	
ARTG Start Date	5/02/2019	
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 . CalmFactors for Juniors

Product Type	Single Medicine Product	Effective Date	19/07/2023
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Permitted Indications

Maintain/support (state vitamin/mineral/nutrient) levels in the body in adults
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy in adults
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy in children
Maintain/support cognitive function/mental function when dietary intake is inadequate in children
Maintain/support cognitive function/mental function when dietary intake is inadequate in adults
Aid/assist/helps synthesis of neurotransmitters in children
Aid/assist/helps synthesis of neurotransmitters in adults
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep in children
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep in adults

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

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.
In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.

Additional Product information



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Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	
Active Ingredients	
choline bitartrate	12.5 mg/mL
inositol	12.5 mg/mL
Melissa officinalis leaf Extract dry concentrate	8.205 mg/mL
Equivalent: Melissa officinalis (Dry)	32 mg/mL
Passiflora incarnata herb Extract dry concentrate	5 mg/mL
Equivalent: Passiflora incarnata (Dry)	25 mg/mL
Valeriana officinalis root Extract dry concentrate	16 mg/mL
Equivalent: Valeriana officinalis (Dry)	64 mg/mL
Other Ingredients (Excipients)	
citric acid	
colloidal anhydrous silica	
Flavour	
glycerol	
maltodextrin	
potassium sorbate	
purified water	
silicon dioxide	
Stevia rebaudiana	
xanthan gum	

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