



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	327661	iThrive Nutrition CHILL OUT
ARTG entry for	Medicine Listed	
Sponsor	Life Trends International Pty Ltd	
Postal Address	PO Box 6884, Baulkham Hills, NSW, 2153 Australia	
ARTG Start Date	13/12/2019	
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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . iThrive Nutrition CHILL OUT

Product Type	Single Medicine Product	Effective Date	13/12/2019
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Permitted Indications

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 Western herbal 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 soporific/induces sleep

Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep

Traditionally used in Western herbal medicine to enhance/promote/increase healthy sleep patterns

Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep 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.

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



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If symptoms persist consult your healthcare practitioner (or words to that effect).

Not for prolonged use. If symptoms persist, seek advice from a health care practitioner. Not recommended for use by pregnant or lactating women (or words to that effect). May harm the liver.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

glycine	100 mg
magnesium amino acid chelate	250 mg
Equivalent: magnesium	50 mg
Magnolia officinalis stem bark Extract dry concentrate	150 mg
Equivalent: Magnolia officinalis (Dry)	1.5 g
Melissa officinalis flower and leaf Extract dry concentrate	75 mg
Equivalent: Melissa officinalis (Dry)	750 mg
Passiflora incarnata herb top flowering Extract dry concentrate	75 mg
Equivalent: Passiflora incarnata (Dry)	1.5 g
Piper methysticum root Extract dry concentrate standardised	400 mg
Equivalent: Piper methysticum (Dry)	4 g
Ziziphus jujuba var. spinosa seed Extract dry concentrate	300 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	3 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
crospovidone
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
povidone

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