



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	262496	ETHICAL NUTRIENTS TRIPLE ACTION SLEEP SUPPORT
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	2/11/2015	
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.

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 . ETHICAL NUTRIENTS TRIPLE ACTION SLEEP SUPPORT

Product Type	Single Medicine Product	Effective Date	19/05/2020
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Permitted Indications

- Traditionally used in Western herbal medicine to analgesic/Anodyne/relieve pain
- Traditionally used in Chinese medicine to calms the mind
- Traditionally used in Western herbal medicine to calms the mind
- Traditionally used in Chinese medicine to aid/assist/helps mind relaxation
- Traditionally used in Western herbal medicine to aid/assist/helps mind relaxation
- Traditionally used in Chinese medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Chinese medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Traditionally used in Western herbal medicine to maintains/supports refreshing sleep
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to decrease/reduce time to fall asleep
- Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Western herbal medicine to maintain/support healthy sleeping patterns
- Traditionally used in Chinese medicine to maintain/support healthy sleeping patterns
- 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.



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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

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

Additional Product information

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

Eschscholzia californica herb flowering Extract dry concentrate	250 mg
Equivalent: Eschscholzia californica (Dry)	1.5 g
Lavender Oil	80 mg
Ziziphus jujuba var. spinosa seed Extract dry concentrate	555.56 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	10 g

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- hypromellose
- macrogol 400
- magnesium stearate
- microcrystalline cellulose
- povidone

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