



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	306813	ETHICAL NUTRIENTS SUPER B DAILY STRESS +
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	9/07/2018	
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 SUPER B DAILY STRESS +

Product Type	Single Medicine Product	Effective Date	25/05/2020
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Permitted Indications

Relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
Traditionally used in Western herbal medicine to enhance/promote body adaptation to stress
Support healthy stress response in the body
Decrease/reduce/relieve symptoms of stress
Maintain/support mental concentration/focus/clarity
Traditionally used in Western herbal medicine to enhance/improve/promote/increase mental endurance/stamina
Traditionally used in Western herbal medicine to maintain/support mental endurance/stamina
Maintain/support nervous system health

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 not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].
If symptoms persist consult your healthcare practitioner (or words to that effect).

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Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	150 mg
calcium pantothenate	100 mg
cyanocobalamin	200 microgram
folic acid	200 microgram
nicotinamide	100 mg
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.14 mg
Rhodiola rosea root Extract dry concentrate	250 mg
Equivalent: Rhodiola rosea (Dry)	1 g
riboflavin	50 mg
thiamine hydrochloride	75 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate
carrageenan
croscarmellose sodium
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
silicon dioxide
tartaric acid

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