



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	297273	METAGENICS HPA ESSENTIALS
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	7/12/2017	
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 . METAGENICS HPA ESSENTIALS

Product Type	Effective Date
Single Medicine Product	30/01/2020

Permitted Indications

Helps reduce/decrease free radical damage to body cells
Maintain/support energy levels
Maintain/support general health and wellbeing
Support healthy stress response in the body
Support healthy stress response in the body
Maintain/support neuroendocrine function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system function

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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].



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

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

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

Biotin	500 microgram
calcium ascorbate dihydrate	545 mg
Equivalent: ascorbic acid	450 mg
calcium pantothenate	300 mg
Citrus bioflavonoids extract	50 mg
levomefolate calcium	217 microgram
Equivalent: levomefolic acid	200 microgram
mecobalamin (co-methylcobalamin)	200 microgram
nicotinamide	50 mg
pyridoxal 5-phosphate monohydrate	50 mg
Equivalent: pyridoxine	32.5 mg
riboflavin sodium phosphate	20 mg
thiamine hydrochloride	50 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
chlorophyllin-copper complex
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
silicon dioxide
stearic acid
tartaric acid

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