



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	343669	METAGENICS ENERGYX CHOCOLATE FLAVOUR
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	17/09/2020	
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 . METAGENICS ENERGYX CHOCOLATE FLAVOUR

Product Type	Single Medicine Product	Effective Date	18/02/2021
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Permitted Indications

- Maintain/support energy levels
- Maintain/support heat/energy production/thermogenesis
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Maintain/support general health and wellbeing
- Maintain/support healthy thyroid hormones
- Aid/assist thyroid hormone production
- Maintain/support muscle function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Decrease/reduce/relieve symptoms of stress
 - Linked indication - Maintain/support cognitive function/mental function
- Maintain/support cognitive function/mental function

Indication Requirements

- Product presentation must not imply or refer to any thyroid related diseases.
- If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings



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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.

Adults only.

The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).

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

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral
Route of Administration Oral

Visual Identification

Active Ingredients

acetyl levocarnitine hydrochloride	126.32 mg/g
ascorbic acid	52.63 mg/g
borax	1.39 mg/g
Equivalent: boron	157.9 microgram/g
calcium hydrogen phosphate dihydrate	226 mg/g
Equivalent: calcium	52.63 mg/g
calcium pantothenate	5.79 mg/g
dibasic sodium phosphate	26.32 mg/g
Equivalent: sodium	8.53 mg/g
magnesium amino acid chelate	210.53 mg/g
Equivalent: magnesium	21.05 mg/g
mecobalamin (co-methylcobalamin)	21.06 microgram/g
nicotinamide	2.63 mg/g
potassium iodide	10.33 microgram/g
Equivalent: iodine	7.89 microgram/g
riboflavin sodium phosphate	2.64 mg/g
Equivalent: riboflavin	1.93 mg/g
selenomethionine	6.58 microgram/g
Equivalent: selenium	2.63 microgram/g
thiamine hydrochloride	2.63 mg/g
tyrosine	105.26 mg/g
zinc amino acid chelate	5.26 mg/g
Equivalent: zinc	1.05 mg/g

Other Ingredients (Excipients)

calcium hydrogen phosphate
citric acid
cocoa powder
colloidal anhydrous silica
Flavour
maltodextrin
potassium bicarbonate
Steviol glycosides

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