



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	276094	Eagle Tresos Energy
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	2/06/2016	
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 . Eagle Tresos Energy

Product Type	Single Medicine Product	Effective Date	7/08/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range
- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support skin health
- Maintain/support skin repair/healing/regeneration

Indication Requirements



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If product is indicated for supplementation, Label statement: 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.

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.

Product presentation must not imply or refer to serious cardiovascular conditions.

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

Product presentation must not imply or refer to serious immunological diseases.

Label statement: 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.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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.

This product 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.

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

For practitioner dispensing only.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

WARNING - this medication may be dangerous when used in large amounts or for a long time; or WARNING - this product contains [insert pyridoxine hydrochloride or pyridoxal 5-phosphate as applicable], which may be dangerous when used in large amounts or for a long time.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

If symptoms persist, seek the advice of a healthcare professional.

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	125 mg/g
ascorbic acid	16.67 mg/g
betacarotene	.6667 mg/g
Beta vulgaris	16.67 mg/g
Biotin	25 microgram/g
bromelains	2.5 mg/g
calcium folinate	92.6 microgram/g
Equivalent: folic acid	66.7 microgram/g
calcium pantothenate	16.01 mg/g
Equivalent: calcium	1.34 mg/g
Equivalent: pantothenic acid	14.67 mg/g
choline bitartrate	25 mg/g
Equivalent: choline	10.28 mg/g

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chromium nicotinate	35 microgram/g
Equivalent: chromium	4.2 microgram/g
Citrus bioflavonoids extract	833 microgram/g
colecalfiferol	.4167 microgram/g
copper gluconate	7.14 microgram/g
Equivalent: copper	1 microgram/g
cysteine hydrochloride	4.17 mg/g
Equivalent: cysteine	2.87 mg/g
d-alpha-tocopheryl acid succinate	4.82 mg/g
dibasic potassium phosphate	5.19 mg/g
Equivalent: potassium	2.33 mg/g
glutamine	6.67 mg/g
hesperidin	833 microgram/g
inositol	4.17 mg/g
lysine hydrochloride	5.83 mg/g
Equivalent: lysine	4.67 mg/g
magnesium citrate	30.94 mg/g
Equivalent: magnesium	5 mg/g
manganese amino acid chelate	83.3 microgram/g
Equivalent: manganese	8.33 microgram/g
mecobalamin (co-methylcobalamin)	66.67 microgram/g
mixed (low-alpha type) tocopherols concentrate	2.25 mg/g
molybdenum trioxide	12.5 microgram/g
Equivalent: molybdenum	8.33 microgram/g
nicotinamide	29.9733 mg/g
nicotinic acid	830 microgram/g
potassium iodide	6.76 microgram/g
Equivalent: iodine	5.17 microgram/g
pyridoxal 5-phosphate monohydrate	2.62 mg/g
Equivalent: pyridoxine	1.67 mg/g
pyridoxine hydrochloride	8.3516 mg/g
retinol palmitate	.2321 mg/g
Rhodiola rosea	33.33 mg/g
Equivalent: Rhodiola rosea	133.32 mg/g
Equivalent: rosavin (of Rhodiola rosea)	666 microgram/g
Equivalent: Salidroside (of Rhodiola rosea)	333 microgram/g
riboflavin sodium phosphate	6.85 mg/g
Equivalent: riboflavin	5 mg/g
Rosa canina	1.67 mg/g
rutoside	1.67 mg/g
selenomethionine	10.76 microgram/g
Equivalent: selenium	4.33 microgram/g
taurine	166.67 mg/g
thiamine nitrate	8.325 mg/g
zinc gluconate	20.42 mg/g
Equivalent: zinc	2.67 mg/g

Other Ingredients (Excipients)

Acacia
Beta vulgaris
citric acid

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colloidal anhydrous silica
dl-alpha-tocopherol
ethylcellulose
Flavour
Gelatin
glycine
maize starch
maltodextrin
medium chain triglycerides
mono- and di- glycerides
potable water
purified water
silicon dioxide
Soya Oil
starch sodium octenyl succinate
Stevia rebaudiana
sucrose
thaumatin

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