



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|---------------------|
| 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.

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 | 20/10/2021 |
|---------------------|-------------------------|-----------------------|------------|

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

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 serious cardiovascular conditions.

Product presentation must not imply or refer to serious immunological 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.

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



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

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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

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

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.

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

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

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 symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

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

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|--------------------------------|--------------|
| 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 root Powder | 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: pantothenic acid | 14.67 mg/g |
| Equivalent: calcium | 1.34 mg/g |
| choline bitartrate | 25 mg/g |
| Equivalent: choline | 10.28 mg/g |
| 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 |

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| | |
|---|--------------------------|
| 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 |
| Equivalent: vitamin A | .1252 mg/g |
| Rhodiola rosea root Extract dry concentrate standardised | 33.33 mg/g |
| Equivalent: Rhodiola rosea (Dry) | 133.32 mg/g |
| riboflavin sodium phosphate | 6.85 mg/g |
| Equivalent: riboflavin | 5 mg/g |
| Rosa canina fruit Dry | 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
colloidal anhydrous silica
dl-alpha-tocopherol
ethylcellulose
Flavour
Gelatin
glycine
maize starch
maltodextrin

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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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