



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322566	Eagle Tresos Activated B PluSe
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	2/09/2019	
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 Activated B PluSe

Product Type	Single Medicine Product	Effective Date	22/04/2022
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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
Aid/assist/helps synthesis of neurotransmitters
Maintain/support skin health
Maintain/support skin repair/healing/regeneration

Indication Requirements

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 serious immunological diseases.

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

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.

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.



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

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.

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

For practitioner dispensing only.

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

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.

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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	10 mg
Biotin	150 microgram
bromelains	6 mg
calcium ascorbate dihydrate	121.04 mg
Equivalent: calcium	11.38 mg
Equivalent: ascorbic acid	100 mg
calcium folinate	278 microgram
Equivalent: folinic acid	200 microgram
calcium pantothenate	100 mg
Equivalent: pantothenic acid	88 mg
Equivalent: calcium	8.4 mg
choline bitartrate	40 mg
chromium nicotinate	208.34 microgram
Equivalent: chromium	25 microgram
Citrus bioflavonoids extract	5 mg
colecalfiferol	.0025 mg
cupric citrate hemipentahydrate	17 microgram
Equivalent: copper	6 microgram
cysteine hydrochloride	21.74 mg
Equivalent: cysteine	15 mg
d-alpha-tocopheryl acid succinate	28 mg
glutamine	40 mg
hesperidin	5 mg

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inositol	25 mg
lecithin	15 mg
levomefolate calcium Equivalent: levomefolic acid	216.56 microgram 200 microgram
lysine hydrochloride Equivalent: lysine	35 mg 28 mg
magnesium phosphate pentahydrate Equivalent: phosphorus Equivalent: magnesium	48.4 mg 8.5 mg 10 mg
manganese gluconate Equivalent: manganese	438.6 microgram 50 microgram
mecobalamin (co-methylcobalamin)	500 microgram
mixed (low-alpha type) tocopherols concentrate	13.5 mg
molybdenum trioxide Equivalent: molybdenum	75 microgram 50 microgram
monobasic potassium phosphate Equivalent: potassium	48.73 mg 14 mg
nicotinamide	220 mg
nicotinic acid	5 mg
potassium iodide Equivalent: iodine Equivalent: potassium	40.55 microgram 31 microgram 9.55 microgram
pyridoxal 5-phosphate monohydrate Equivalent: pyridoxine	10 mg 6.38 mg
pyridoxine hydrochloride Equivalent: pyridoxine	50.13 mg 40 mg
retinol acetate Equivalent: vitamin A	.8843 mg .7497 mg
riboflavin sodium phosphate Equivalent: riboflavin	27.4 mg 20 mg
Rosa canina fruit Powder	10 mg
rutoside	10 mg
selenomethionine Equivalent: selenium	64.58 microgram 26 microgram
taurine	85 mg
thiamine hydrochloride Equivalent: thiamine	50 mg 43.26 mg
zinc gluconate Equivalent: zinc	109.88 mg 14.35 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
crospovidone
dl-alpha-tocopherol
ethylcellulose
hydrogenated soya oil
hydrolysed gelatin

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hypromellose
macrogol 8000
magnesium stearate
maize starch
maltodextrin
microcrystalline cellulose
potable water
povidone
silicon dioxide
Soya Oil
spray-dried glucose syrup
sucrose
tartaric acid

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