



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		401891	Eagle Tresos-B
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	6/01/2023		
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-B

Product Type	Single Medicine Product	Effective Date	18/01/2023
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Maintain/support collagen health
Helps convert (state food) into energy
Maintain/support energy production
Maintain/support healthy eye function
Maintain/support eye health
Helps maintain/support eye retina health
Maintain/support healthy eyesight/vision
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support artery health
Maintain/support blood capillary health
Maintain/support blood vessel 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
Support healthy stress response in the body
Maintain/support cognitive function/mental function
Maintain/support brain function



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Aid/assist/helps synthesis of neurotransmitters
Maintain/support skin health
Maintain/support skin regeneration
Maintain/support skin repair/healing/regeneration

Indication Requirements

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

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 serious cardiovascular conditions.

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

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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.

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.

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.

For practitioner dispensing only.

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

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.

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	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
betacarotene	6 mg
Biotin	50 microgram
calcium hydrogen phosphate dihydrate	50 mg
Equivalent: calcium	11.62 mg
calcium pantothenate	100 mg
Equivalent: pantothenic acid	91.61 mg



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Equivalent: calcium	8.39 mg
choline bitartrate	50 mg
chromic chloride hexahydrate	20.5 microgram
Equivalent: chromium	4 microgram
colecalfiferol	.0025 mg
cupric sulfate pentahydrate	23.6 microgram
Equivalent: copper	6 microgram
cyanocobalamin	100 microgram
d-alpha-tocopheryl acid succinate	50 mg
folic acid	150 microgram
glutamine	50 mg
inositol	25 mg
lecithin	50 mg
lysine hydrochloride	50 mg
Equivalent: lysine	40 mg
magnesium aspartate dihydrate	10.67 mg
Equivalent: magnesium	800 microgram
magnesium phosphate pentahydrate	33.88 mg
Equivalent: magnesium	7 mg
manganese sulfate monohydrate	500 microgram
Equivalent: manganese	162.5 microgram
molybdenum trioxide	69.9 microgram
Equivalent: molybdenum	46.6 microgram
nicotinamide	220 mg
nicotinic acid	5 mg
potassium aspartate	13.82 mg
Equivalent: potassium	3 mg
potassium iodide	40.5 microgram
Equivalent: iodine	31 microgram
Equivalent: potassium	9.54 microgram
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.14 mg
retinol acetate	.8846 mg
Equivalent: vitamin A	.7499 mg
riboflavin	20 mg
taurine	125 mg
thiamine hydrochloride	50 mg
tribasic potassium phosphate	30 mg
Equivalent: potassium	14 mg
zinc gluconate	110.26 mg
Equivalent: zinc	14.4 mg

Other Ingredients (Excipients)

Acacia
betaine hydrochloride
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
ethylcellulose
hypromellose

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iron oxide black
macrogol 400
macrogol 8000
magnesium stearate
maize starch
medium chain triglycerides
microcrystalline cellulose
Pea Starch
povidone
purified water
silicon dioxide
sodium alginate
spray-dried glucose syrup
sucrose
vanillin

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