



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	310944	BioTress
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	31/10/2018	
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 . BioTress

Product Type	Single Medicine Product	Effective Date	22/08/2019
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Maintain/support energy production
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Maintain/support hair growth
Maintain/support hair health
Maintain/support nail health/strength/thickness
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Helps maintain/supports healthy joint cartilage growth/development/production
Helps maintain/support joint cartilage health
Aid/assist healthy red blood cell production
Maintain/support red blood cell health

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Helps maintain/support healthy cholesterol
Helps maintain/support healthy blood sugar/glucose
Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support blood capillary health
Maintain/support blood vessel health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral) within normal range
Support healthy stress response in the body
Maintain/support cognitive function/mental function
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract
Maintain/support skin health
Maintain/support wound healing
Maintain/support skin repair/healing/regeneration

Indication Requirements

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

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

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.

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

Product presentation must not imply or refer to hormone imbalances.

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.

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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

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 lowering or raising blood cholesterol levels from outside of the normal healthy range

Product presentation must not imply or refer to infertility.

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



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Warnings

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

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.

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.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	100 mg
Biotin	50 microgram
calcium folinate	114 microgram
Equivalent: folic acid	105 microgram
calcium pantothenate	75 mg
Equivalent: pantothenic acid	68.71 mg
calcium phosphate	12.9 mg
Equivalent: calcium	5 mg
choline bitartrate	25 mg
chromium picolinate	200 microgram
Equivalent: chromium	25 microgram
Citrus bioflavonoids extract	12.5 mg
colecalfiferol	.0062 mg
colloidal anhydrous silica	12.83 mg
Equivalent: silicon	6 mg
copper gluconate	360 microgram
Equivalent: copper	50 microgram
cyanocobalamin	200 microgram
d-alpha-tocopheryl acid succinate	41.32 mg
Equivalent: d-alpha-tocopherol	50 IU
folic acid	95 microgram
hesperidin	7.5 mg
inositol	12.5 mg
magnesium amino acid chelate	50 mg
Equivalent: magnesium	10 mg
manganese amino acid chelate	5 mg
Equivalent: manganese	500 microgram
molybdenum trioxide	75 microgram
Equivalent: molybdenum	50 microgram
nicotinamide	107.5 mg
nicotinic acid	2.5 mg
Peppermint Oil	1 mg
phytomenadione	.05 mg
potassium citrate	12.44 mg

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Equivalent: potassium	4.5 mg
potassium iodide	85 microgram
Equivalent: iodine	65 microgram
pyridoxal 5-phosphate monohydrate	10.74 mg
Equivalent: pyridoxine	6.85 mg
pyridoxine hydrochloride	10 mg
Equivalent: pyridoxine	8.23 mg
retinol acetate	.1771 mg
riboflavin	15 mg
rutoside	2.5 mg
selenomethionine	62 microgram
Equivalent: selenium	25 microgram
thiamine hydrochloride	41.24 mg
Equivalent: thiamine	32.45 mg
zinc citrate dihydrate	23.36 mg
Equivalent: zinc	7.5 mg

Other Ingredients (Excipients)

Acacia
chlorophyllin-copper complex
colloidal anhydrous silica
d-alpha-tocopherol
disodium edetate
dl-alpha-tocopherol
ethylcellulose
gellan gum
hypromellose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
potassium acetate
purified water
silicon dioxide
sodium ascorbate
sorbitan monolaurate
sucrose

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