



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	186016	ORTHOPLEX B VITAL POWDER
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	28/06/2011	
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 . ORTHOPLEX B VITAL POWDER

Product Type	Single Medicine Product	Effective Date	16/09/2021
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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 natural liver cleansing/detoxification processes
Maintain/support energy production
Maintain/support eye health
Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Maintain/support hair growth
Maintain/support hair health
Maintain/support healthy teeth
Maintain/support nail health/strength/thickness
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Helps maintain/support joint cartilage health
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Helps maintain/support healthy blood sugar/glucose
Maintain/support blood health
Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support blood capillary health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production

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Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support bile production
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Maintain/support muscle function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps decrease/reduce homocysteine levels in healthy individuals
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps maintain/support cellular uptake of (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Support healthy stress response in the body
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

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

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.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

Product presentation must only refer to detoxification in relation to natural body processes.

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 circulatory disorders/diseases/conditions e.g. thrombosis.

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

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

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).

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 drugs/alcohol.

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

Warnings

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.



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Adults only.

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

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

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

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

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**

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	4.44 mg/g
ascorbic acid	22.22 mg/g
Biotin	11.11 microgram/g
calcium ascorbate	22.22 mg/g
Equivalent: calcium	2.09 mg/g
Equivalent: ascorbic acid	18.25 mg/g
calcium hydrogen phosphate dihydrate	19.08 mg/g
Equivalent: calcium	4.44 mg/g
calcium pantothenate	22.22 mg/g
Equivalent: pantothenic acid	20.35 mg/g
Camellia sinensis leaf Extract dry concentrate	1.11 mg/g
Equivalent: Camellia sinensis (Dry)	11.1 mg/g
chromium picolinate	80.45 microgram/g
Equivalent: chromium	10 microgram/g
Citrus bioflavonoids extract	11.11 mg/g
colecalfiferol	.5555 microgram/g
copper gluconate	15.86 microgram/g
Equivalent: copper	2.22 microgram/g
cyanocobalamin	22.22 microgram/g
cysteine hydrochloride	2.22 mg/g
d-alpha-tocopheryl acetate	8.173 mg/g
folic acid	40 microgram/g
glutamine	11.11 mg/g
glycine	360.15 mg/g
lecithin	22.22 mg/g
levocarnitine fumarate	4.44 mg/g
magnesium phosphate pentahydrate	10.76 mg/g
Equivalent: magnesium	2.22 mg/g
manganese amino acid chelate	222.22 microgram/g
Equivalent: manganese	22.22 microgram/g
monobasic potassium phosphate	7.74 mg/g
Equivalent: potassium	2.22 mg/g
nicotinamide	44.44 mg/g

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nicotinic acid	1.11 mg/g
pyridoxal 5-phosphate	6.66 mg/g
Equivalent: pyridoxine	4.56 mg/g
retinol palmitate	111.3139 microgram/g
Equivalent: vitamin A	60.0615 microgram/g
riboflavine	4.44 mg/g
selenomethionine	5.55 microgram/g
Equivalent: selenium	2.22 microgram/g
taurine	22.22 mg/g
thiamine hydrochloride	11.11 mg/g
tyrosine	11.11 mg/g
zinc amino acid chelate	11.11 mg/g
Equivalent: zinc	2.22 mg/g

Other Ingredients (Excipients)

Acacia
calcium carbonate
calcium hydrogen phosphate dihydrate
citric acid
dl-alpha-tocopherol
Flavour
Gelatin
maize starch
malic acid
medium chain triglycerides
potassium bicarbonate
silicon dioxide
sodium bicarbonate
Stevia rebaudiana
sucrose

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