



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299281	Orthoplex Clinical C
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	2/02/2018	
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.

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 Clinical C

Product Type	Single Medicine Product	Effective Date	21/12/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Aids/assists natural body cleansing/detoxification processes
Maintain/support natural body cleansing/detoxification processes
Maintain/support natural liver cleansing/detoxification processes
Maintain/support energy production
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support healthy eyesight/vision
Maintain/support general health and wellbeing
Maintain/support healthy teeth
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
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
Maintain/support bile production



Australian Government
Department of Health
Therapeutic Goods Administration

Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
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 in athletes
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy individuals
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones in healthy males
Maintain/support sperm production
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration

Indication Requirements

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 vision correction, faults or serious eye disease e.g. macular degeneration.
Product presentation must not imply or refer to any thyroid related 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 drugs/alcohol.
Product presentation must only refer to detoxification in relation to natural body processes.
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 serious cardiovascular conditions.
Product presentation must not imply or refer to serious immunological diseases.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to infertility.
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 mental illnesses, disorders or 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.
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 hormone imbalances.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.
Not recommended for use by pregnant and lactating women (or words to that effect).
The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).
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



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	20 mg
calcium ascorbate dihydrate	726.39 mg
Equivalent: ascorbic acid	600 mg
glutathione	10 mg
hesperidin	25 mg
nicotinamide	5 mg
palm tocotrienols complex	2.001 mg
pyridoxal 5-phosphate monohydrate	2.19 mg
Equivalent: pyridoxine	1.5 mg
rutoside	25 mg
selenomethionine	38 microgram
Equivalent: selenium	15 microgram
sodium ascorbate	452.49 mg
Equivalent: ascorbic acid	400 mg

Other Ingredients (Excipients)

ascorbyl palmitate
calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
microcrystalline cellulose
Palm Fruit Oil
starch sodium octenyl succinate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary