



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	153257	Orthoplex Joint Tissue Support
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	24/06/2008	
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 Joint Tissue Support

Product Type	Single Medicine Product	Effective Date	27/11/2020
---------------------	-------------------------	-----------------------	------------

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 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
- 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 smell sensation
- Maintain/support taste sensation
- Maintain/support bile production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Aid/assist/helps protein synthesis in the body
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Support healthy stress response in the body
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 immunological diseases.
Product presentation must only refer to detoxification in relation to natural body processes.
Product presentation must not imply or refer to serious cardiovascular conditions.
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 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.
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 any thyroid related diseases.
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 disease in any body organ, in particular the kidney or liver.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
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).
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 drugs/alcohol.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.
Contains potassium. If you have kidney disease or are taking heart or blood pressure medicines, consult your doctor or pharmacist before use. Keep out of reach of children.
Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
Seek professional advice before long term use.
Derived from seafood.
If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Visual Identification

Active Ingredients

ascorbic acid	83.33 mg/g
borax	2.7 mg/g
Equivalent: boron	.31 mg/g
bovine sodium chondroitin sulfate	16.67 mg/g
Equivalent: chondroitin sulfate	15 mg/g
calcium pantothenate	5 mg/g
Equivalent: pantothenic acid	4.58 mg/g
Citrus bioflavonoids extract	55 mg/g
copper gluconate	641 microgram/g
Equivalent: copper	83.33 microgram/g
creatine monohydrate	83.33 mg/g
glucosamine hydrochloride	83.33 mg/g
Equivalent: glucosamine	69.17 mg/g
glucosamine sulfate potassium chloride	83.33 mg/g
Equivalent: glucosamine	49.26 mg/g
Equivalent: potassium chloride	20.52 mg/g
glycine	243.5 mg/g
leucine	33.33 mg/g
lysine hydrochloride	100 mg/g
selenomethionine	18.13 microgram/g
Equivalent: selenium	7.25 microgram/g
valine	33.33 mg/g
zinc amino acid chelate	4.17 mg/g
Equivalent: zinc	.834 mg/g

Other Ingredients (Excipients)

ascorbyl palmitate
betacarotene
citric acid
colloidal anhydrous silica
Flavour
Gelatin
malic acid
mixed (low-alpha type) tocopherols concentrate
potable water
silicon dioxide
Soya Oil
Stevia rebaudiana
sucrose
tapioca starch

© 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