



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

| | | |
|--------------------------------|---|-----------------------|
| Summary for ARTG Entry: | 267041 | Orthoplex MagOpticell |
| ARTG entry for | Medicine Listed | |
| Sponsor | Bio Concepts Pty Ltd | |
| Postal Address | PO Box 190, Banyo, Brisbane, QLD, 4014 Australia | |
| ARTG Start Date | 12/01/2016 | |
| 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 MagOpticell

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 2/03/2021 |
|---------------------|-------------------------|-----------------------|-----------|

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 heat/energy production/thermogenesis
- 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
- Aids/assists healthy bone development/growth/building
- Helps maintain/supports healthy joint cartilage growth/development/production
- 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
- Helps maintain/support healthy heart function
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Maintain/support blood capillary health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
Maintain/support bile production
Maintain/support immune system health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Maintain/support immune system to fight illness
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps decrease/reduce homocysteine levels
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
Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes
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
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support nerve conduction
Maintain/support nerve conduction
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support preconception health
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing
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 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 circulatory disorders/diseases/conditions e.g. thrombosis.

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 any thyroid related diseases.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

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).

Label statement: If symptoms persist, talk to your health professional.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Product presentation must not imply or refer to drugs/alcohol.

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.



Australian Government
Department of Health
 Therapeutic Goods Administration

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

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

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 only refer to mild anxiety.

Product presentation must not imply or refer to infertility.

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 serious musculoskeletal or neurological conditions.

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.

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.

If symptoms persist, seek the advice of a healthcare professional.

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

| | |
|---|--------------------------|
| ascorbic acid | 30.77 mg/g |
| calcium folinate | 83.1 microgram/g |
| Equivalent: folic acid | 76.92 microgram/g |
| calcium pantothenate | 25.2 mg/g |
| Equivalent: pantothenic acid | 23.08 mg/g |
| chromium nicotinate | 61.54 microgram/g |
| Equivalent: chromium | 7.69 microgram/g |
| creatine monohydrate | 153.85 mg/g |
| cyanocobalamin | 61.56 microgram/g |
| glutamine | 76.92 mg/g |
| levocarnitine | 10.77 mg/g |
| magnesium amino acid chelate | 163.7 mg/g |
| Equivalent: magnesium | 23.08 mg/g |
| magnesium citrate | 99.6 mg/g |
| Equivalent: magnesium | 15.39 mg/g |
| magnesium orotate dihydrate | 70 mg/g |
| Equivalent: magnesium | 4.62 mg/g |
| magnesium phosphate pentahydrate | 22.34 mg/g |
| Equivalent: magnesium | 4.62 mg/g |
| manganese amino acid chelate | 1.54 mg/g |
| Equivalent: manganese | 154 microgram/g |
| monobasic potassium phosphate | 26.77 mg/g |



Australian Government
Department of Health
Therapeutic Goods Administration

| | |
|---------------------------------------|-------------------------|
| Equivalent: potassium | 7.69 mg/g |
| nicotinamide | 7.7 mg/g |
| potassium citrate | 35.17 mg/g |
| Equivalent: potassium | 12.31 mg/g |
| pyridoxal 5-phosphate | 1.54 mg/g |
| Equivalent: pyridoxine | 1.05 mg/g |
| riboflavin sodium phosphate | 1.54 mg/g |
| Equivalent: riboflavin | 1.17 mg/g |
| selenomethionine | 9.61 microgram/g |
| Equivalent: selenium | 3.84 microgram/g |
| taurine | 76.92 mg/g |
| thiamine hydrochloride | 4.63 mg/g |
| Equivalent: thiamine | 4.13 mg/g |
| zinc amino acid chelate | 3.85 mg/g |
| Equivalent: zinc | .77 mg/g |
| Other Ingredients (Excipients) | |
| Flavour | |
| malic acid | |
| Stevia rebaudiana | |

© 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