



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	265520	Orthoplex MagTaur Xcell
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	7/12/2015	
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 . Orthoplex MagTaur Xcell

Product Type	Single Medicine Product	Effective Date	18/06/2019
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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 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 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/support joint cartilage health

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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 heart health
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 healthy immune system function
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
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
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
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 in healthy individuals

Indication Requirements

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

Product presentation must not imply or refer to hormone imbalances.

Label statement: 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.

If product is indicated for supplementation, Label statement: 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.

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

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

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
 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 serious musculoskeletal or neurological conditions.
 Product presentation must not imply or refer to infertility.
 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 immunological diseases.
 Product presentation must not imply or refer to any thyroid related diseases.
 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 drugs/alcohol.
 Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
 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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

calcium folinate	11.54 microgram/g
Equivalent: folinic acid	10.68 microgram/g
calcium pantothenate	17.5 mg/g
Equivalent: calcium	1.47 mg/g
Equivalent: pantothenic acid	16.03 mg/g
glutamine	53.43 mg/g
hydroxocobalamin	10.68 microgram/g
levomefolate calcium	46.32 microgram/g
Equivalent: calcium	3.59 microgram/g
Equivalent: levomefolic acid	42.73 microgram/g
magnesium ascorbate monohydrate	74.19 mg/g
Equivalent: magnesium	4.6 mg/g
Equivalent: ascorbic acid	66.55 mg/g
magnesium citrate	49.51 mg/g
Equivalent: magnesium	8.02 mg/g
magnesium glycinate dihydrate	182.66 mg/g
Equivalent: magnesium	21.37 mg/g
magnesium orotate	51.81 mg/g
Equivalent: magnesium	3.42 mg/g
mecobalamin (co-methylcobalamin)	42.74 microgram/g

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

nicotinamide	1.07 mg/g
pyridoxal 5-phosphate	1.17 mg/g
Equivalent: pyridoxine	.8 mg/g
pyridoxine hydrochloride	1.95 mg/g
Equivalent: pyridoxine	1.6 mg/g
riboflavin sodium phosphate	1.07 mg/g
Equivalent: riboflavin	.82 mg/g
taurine	320.57 mg/g
thiamine hydrochloride	2.14 mg/g
Equivalent: thiamine	1.91 mg/g
zinc citrate dihydrate	5.14 mg/g
Equivalent: zinc	1.61 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica
Flavour
malic acid
Stevia rebaudiana

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Public Summary