



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>		265520	Orthoplex MagTaur Xcell
<b>ARTG entry for</b>	Medicine Listed		
<b>Sponsor</b>	Bio Concepts Pty Ltd		
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia		
<b>ARTG Start Date</b>	7/12/2015		
<b>Product Category</b>	Medicine		
<b>Status</b>	Active		
<b>Approval Area</b>	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 MagTaur Xcell

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	16/02/2023
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### Permitted Indications

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 cardiovascular system health  
Helps maintain/support healthy heart function  
Maintain/support healthy cardiovascular system function  
Maintain/support heart health  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
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 (state vitamin/mineral/nutrient) levels in the body  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes  
Support healthy stress response in the body  
Maintain/support brain function  
Maintain/support brain health  
Maintain/support nerve conduction  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Maintain/support nervous system function  
Support healthy emotional/mood balance

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Maintain/support female reproductive system health  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones

#### Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.  
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 cardiovascular conditions.  
Product presentation must not imply or refer to any thyroid related diseases.  
Product presentation must not imply or refer to infertility.  
Product presentation must not imply or refer to hormone imbalances.  
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).

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### 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

<b>calcium folinate</b>	<b>11.54 microgram/g</b>
Equivalent: folinic acid	10.68 microgram/g
<b>calcium pantothenate</b>	<b>17.5 mg/g</b>
Equivalent: calcium	1.47 mg/g
Equivalent: pantothenic acid	16.03 mg/g
<b>glutamine</b>	<b>53.43 mg/g</b>
<b>hydroxocobalamin</b>	<b>10.68 microgram/g</b>
<b>levomefolate calcium</b>	<b>46.32 microgram/g</b>
Equivalent: levomefolic acid	42.73 microgram/g
Equivalent: calcium	3.59 microgram/g
<b>magnesium ascorbate monohydrate</b>	<b>74.19 mg/g</b>
Equivalent: magnesium	4.6 mg/g
Equivalent: ascorbic acid	66.55 mg/g
<b>magnesium citrate</b>	<b>49.51 mg/g</b>
Equivalent: magnesium	8.02 mg/g
<b>magnesium glycinate dihydrate</b>	<b>182.66 mg/g</b>
Equivalent: magnesium	21.37 mg/g
<b>magnesium orotate</b>	<b>51.81 mg/g</b>
Equivalent: magnesium	

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<b>mecobalamin (co-methylcobalamin)</b>	3.42 mg/g
<b>nicotinamide</b>	<b>42.74 microgram/g</b>
<b>pyridoxal 5-phosphate</b>	<b>1.07 mg/g</b>
Equivalent: pyridoxine	<b>1.17 mg/g</b>
<b>pyridoxine hydrochloride</b>	.8 mg/g
Equivalent: pyridoxine	<b>1.95 mg/g</b>
<b>riboflavin sodium phosphate</b>	1.6 mg/g
Equivalent: riboflavin	<b>1.07 mg/g</b>
<b>taurine</b>	.82 mg/g
<b>thiamine hydrochloride</b>	<b>320.57 mg/g</b>
Equivalent: thiamine	<b>2.14 mg/g</b>
<b>zinc citrate dihydrate</b>	1.91 mg/g
Equivalent: zinc	<b>5.14 mg/g</b>
<b>1.61 mg/g</b>	
<b>Other Ingredients (Excipients)</b>	
<b>colloidal anhydrous silica</b>	
<b>Flavour</b>	
<b>malic acid</b>	
<b>Stevia rebaudiana</b>	

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