

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: Orthoplex MagTaur Xcell 265520

ARTG entry for Medicine Listed

Sponsor Bio Concepts Pty Ltd

Postal Address PO Box 190, Banyo, Brisbane, QLD, 4014

7/12/2015 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

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

Product Type Effective Date 29/05/2025 Single Medicine Product

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 vision correction, faults or serious eye disease e.g. macular degeneration.

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

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

Product presentation must not imply or refer to any thyroid related diseases.

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 hormone imbalances

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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

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 53.43 mg/g glutamine hydroxocobalamin 10.68 microgram/g levomefolate calcium 46.32 microgram/g Equivalent: levomefolic acid 42.73 microgram/g

Equivalent: calcium

magnesium ascorbate monohydrate

Equivalent: magnesium

Equivalent: ascorbic acid

fequivalent: ascorbic acid

fequivalent: ascorbic acid

fequivalent: ascorbic acid

fequivalent: magnesium

magnesium glycinate dihydrate182.66 mg/gEquivalent: magnesium21.37 mg/g

magnesium orotate 51.81 mg/g

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Equivalent: magnesium 3.42 mg/g

mecobalamin 42.74 microgram/g

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 phosphate1.07 mg/gEquivalent: riboflavin.82 mg/g

taurine320.57 mg/gthiamine hydrochloride2.14 mg/gEquivalent: thiamine1.91 mg/g

zinc citrate dihydrate5.14 mg/gEquivalent: zinc1.61 mg/g

Other Ingredients (Excipients)

colloidal anhydrous silica

Flavour

malic acid Stevia rebaudiana

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