Public Summary

Summary for ARTG Entry:	401952 MagOpticell
ARTG entry for	Medicine Listed
Sponsor	Bio Concepts Pty Ltd
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia
ARTG Start Date	9/01/2023
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 . MagOpticell

Product Type Single Medicine Product **Effective Date** 9/01/2023

Permitted Indications

Maintain/support energy production
Maintain/support general health and wellbeing
Maintain/support healthy teeth
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Maintain/support cardiovascular system health
Helps maintain/support healthy heart function
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support bile production
Maintain/support immune system health
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Support healthy stress response in the body
Maintain/support nerve conduction
Maintain/support neuromuscular function
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

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 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 serious musculoskeletal or neurological 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).

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.

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.

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	**28.57 mg/g**
calcium folinate	**77.1 microgram/g**
Equivalent: folinic acid	71.4 microgram/g
calcium pantothenate	**23.4 mg/g**
Equivalent: pantothenic acid	21.43 mg/g
chromium nicotinate	**57.1 microgram/g**
Equivalent: chromium	7.14 microgram/g
creatine monohydrate	**142.86 mg/g**
cyanocobalamin	**57.2 microgram/g**
glutamine	**71.43 mg/g**
levocarnitine	**71.43 mg/g**
magnesium amino acid chelate	**152 mg/g**
Equivalent: magnesium	21.43 mg/g
magnesium citrate nonahydrate	**120.2 mg/g**
Equivalent: magnesium	14.29 mg/g
magnesium orotate dihydrate	**65 mg/g**
Equivalent: magnesium	4.29 mg/g
magnesium phosphate pentahydrate	**20.76 mg/g**
Equivalent: magnesium	4.29 mg/g
manganese amino acid chelate	**1.43 mg/g**
Equivalent: manganese	143 microgram/g
nicotinamide	**7.15 mg/g**
potassium citrate	**39.51 mg/g**
Equivalent: potassium	14.29 mg/g
pyridoxal 5-phosphate monohydrate	**1.53 mg/g**

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Equivalent: pyridoxine	975 microgram/g
riboflavin sodium phosphate	**1.72 mg/g**
Equivalent: riboflavin	1.31 mg/g
selenomethionine	**9 microgram/g**
Equivalent: selenium	3.6 microgram/g
taurine	**71.43 mg/g**
thiamine hydrochloride	**4.31 mg/g**
Equivalent: thiamine	3.84 mg/g
zinc amino acid chelate	**3.58 mg/g**
Equivalent: zinc	.715 mg/g

Other Ingredients (Excipients)

Flavour

malic acid

Stevia rebaudiana

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