



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	333696	Mito Xcell
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	8/04/2020	
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 . Mito Xcell

Product Type	Single Medicine Product	Effective Date	21/12/2020
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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 collagen health
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support energy levels
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support general health and wellbeing
- 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
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support blood capillary health
- Maintain/support healthy thyroid gland function
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Maintain/support smell sensation
- Maintain/support taste sensation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy muscle contraction function
- Maintain/support muscle health
- Maintain/support muscle function

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Maintain/support healthy neuromuscular system/function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps protein synthesis in the body
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)
Decrease/reduce/relieve symptoms of mild anxiety
Decrease/reduce/relieve symptoms of mild anxiety
Maintain/support brain function
Maintain/support brain health
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support preconception health
Maintain/support reproductive system health in healthy males
Maintain/support healthy reproductive hormones
Maintain/support sperm health
Maintain/support sperm motility
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 any thyroid related diseases.
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 mild anxiety.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to serious immunological diseases.
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 cardiovascular conditions.
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 chronic fatigue syndrome.
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 drugs/alcohol.
Product presentation must only refer to detoxification in relation to natural body processes.
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 serious musculoskeletal or neurological 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



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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.

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 symptoms persist, seek the advice of a healthcare professional.

Do not take while on warfarin therapy without medical advice.

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

acetyl levocarnitine hydrochloride	125 mg/g
alpha lipoic acid	6.25 mg/g
Biotin	375 microgram/g
calcium pantothenate	12.5 mg/g
Equivalent: pantothenic acid	11.45 mg/g
inositol	125 mg/g
levocarnitine	31.25 mg/g
magnesium citrate	231.48 mg/g
Equivalent: magnesium	37.5 mg/g
manganese amino acid chelate	2.5 mg/g
Equivalent: manganese	.25 mg/g
nicotinamide	6.25 mg/g
palm tocotrienols complex	.624 mg/g
Reynoutria japonica root Extract dry concentrate	25 mg/g
Equivalent: Reynoutria japonica (Dry)	2.5 g/g
riboflavin sodium phosphate	1.25 mg/g
Equivalent: riboflavin	.95 mg/g
rutoside	93.75 mg/g
selenomethionine	18.6 microgram/g
Equivalent: selenium	7.5 microgram/g
ubidecarenone	3.75 mg/g
zinc citrate dihydrate	3.99 mg/g
Equivalent: zinc	1.25 mg/g

Other Ingredients (Excipients)

- colloidal anhydrous silica**
- Flavour**
- glycine**
- malic acid**
- Palm Fruit Oil**
- starch sodium octenyl succinate**
- Stevia rebaudiana**

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