



Australian Government

Department of Health, Disability and Ageing
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	23/10/2025
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Permitted Indications

Maintain/support energy levels
Maintain/support energy production
Maintain/support general health and wellbeing
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support healthy thyroid gland function
Maintain/support thyroid gland 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
Maintain/support neuromuscular function
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance

Indication Requirements

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 any thyroid related diseases.

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

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

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record



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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.

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 trihydrate	102.1 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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