



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	316823	Mito Pro
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	24/04/2019	
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 Pro

Product Type	Single Medicine Product	Effective Date	26/11/2020
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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
- Aids/assists natural body cleansing/detoxification processes
- Maintain/support natural body cleansing/detoxification processes
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support energy production
- Traditionally used in Western herbal medicine to maintain/support physical endurance/capacity/stamina
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Traditionally used in Western herbal medicine to restorative tonic
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support healthy teeth
- Maintain/support nail health/strength/thickness
- 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/support joint cartilage health
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis

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Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
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 bile production in healthy individuals
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 healthy neuromuscular system/function
Traditionally used in Western herbal medicine to help enhance/improve/promote/increase muscle performance/endurance/stamina
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps decrease/reduce homocysteine levels
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals
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)
Support healthy stress response in the body
Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Maintain/support brain function
Maintain/support brain health
Traditionally used in Western herbal medicine to nerve tonic
Maintain/support nerve conduction
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Traditionally used in Western herbal medicine to maintain/support nervous system health
Traditionally used in Western herbal medicine to maintain/support nervous system function
Maintain/support nervous system function
Support healthy emotional/mood balance
Traditionally used in Western herbal medicine to support healthy emotional/mood balance
Maintain/support female reproductive system health
Traditionally used in Western herbal medicine to maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support preconception health in healthy individuals
Traditionally used in Western herbal medicine to maintain/support reproductive system health
Maintain/support reproductive system health in healthy males
Maintain/support healthy reproductive hormones
Traditionally used in Western herbal medicine to aphrodisiac/Enhance/improve/promote healthy libido
Traditionally used in Western herbal medicine to male tonic
Maintain/support sperm health
Maintain/support sperm motility
Maintain/support sperm production
Maintain/support skin health
Maintain/support skin integrity/structure

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Maintain/support wound healing in healthy individuals
 Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to drugs/alcohol.

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 serious immunological diseases.

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 only refer to detoxification in relation to natural body processes.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to hormone imbalances.

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 chronic fatigue syndrome.

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 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 only refer to mild anxiety.

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 form of arthritis or osteoarthritis unless qualified as mild.

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

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

Do not take while on warfarin therapy without medical advice.

If symptoms persist consult your healthcare practitioner (or words to that effect).

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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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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

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ascorbic acid	125 mg/g
Biotin	.0625 mg/g
calcium folinate Equivalent: folic acid	.027 mg/g .025 mg/g
calcium pantothenate Equivalent: pantothenic acid	18.75 mg/g 17.18 mg/g
levocarnitine	250 mg/g
magnesium citrate Equivalent: magnesium	239.2 mg/g 38.75 mg/g
mecobalamin (co-methylcobalamin)	.025 mg/g
nicotinamide	6.25 mg/g
palm tocotrienols complex	.624 mg/g
pyridoxal 5-phosphate monohydrate Equivalent: pyridoxine	1.25 mg/g .8 mg/g
pyridoxine hydrochloride Equivalent: pyridoxine	2.5 mg/g 2.06 mg/g
riboflavin sodium phosphate Equivalent: riboflavin	2.5 mg/g 1.9 mg/g
selenomethionine Equivalent: selenium	31 microgram/g 12.5 microgram/g
thiamine nitrate Equivalent: thiamine	12.5 mg/g 10.13 mg/g
Turnera diffusa leaf Extract dry concentrate Equivalent: Turnera diffusa (Dry)	37.5 mg/g 187.5 mg/g
ubidecarenone	12.5 mg/g
zinc citrate dihydrate Equivalent: zinc	9.984 mg/g 3.125 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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