



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	6/06/2023
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Maintain/support energy levels
Maintain/support energy production
Maintain/support general health and wellbeing
Aid/assist healthy red blood cell production
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Maintain/support muscle function
Maintain/support muscle performance/endurance/stamina
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 brain function
Maintain/support brain health
Maintain/support nerve conduction
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance
Maintain/support female reproductive system health
Maintain/support preconception health in healthy individuals
Maintain/support reproductive system health in healthy males
Maintain/support reproductive system health in healthy individuals
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 maintain/support healthy sexual function
Maintain/support sperm health
Maintain/support sperm motility

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Indication Requirements

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 chronic fatigue syndrome.

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.

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

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.

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.

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

acetyl levocarnitine hydrochloride	125 mg/g
alpha lipoic acid	6.25 mg/g
ascorbic acid	125 mg/g
Biotin	.0625 mg/g
calcium folinate	.027 mg/g
Equivalent: folic acid	.025 mg/g
calcium pantothenate	18.75 mg/g
Equivalent: pantothenic acid	17.18 mg/g
levocarnitine	250 mg/g
magnesium citrate	239.2 mg/g
Equivalent: magnesium	38.75 mg/g
mecobalamin	.025 mg/g
nicotinamide	6.25 mg/g
palm tocotrienols complex	.624 mg/g
pyridoxal 5-phosphate monohydrate	1.25 mg/g
Equivalent: pyridoxine	.8 mg/g
pyridoxine hydrochloride	2.5 mg/g
Equivalent: pyridoxine	2.06 mg/g
riboflavin sodium phosphate	2.5 mg/g



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Equivalent: riboflavin	1.9 mg/g
selenomethionine	31 microgram/g
Equivalent: selenium	12.5 microgram/g
thiamine nitrate	12.5 mg/g
Equivalent: thiamine	10.13 mg/g
Turnera diffusa leaf Extract dry concentrate	37.5 mg/g
Equivalent: Turnera diffusa (Dry)	187.5 mg/g
ubidecarenone	12.5 mg/g
zinc citrate dihydrate	9.984 mg/g
Equivalent: zinc	3.125 mg/g

Other Ingredients (Excipients)

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary