



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|------------|
| 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 |
|---------------------|-------------------------|-----------------------|------------|

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.

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

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 serious immunological diseases.
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 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 serious musculoskeletal or neurological conditions.
Product presentation must not imply or refer to hormone imbalances.
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.

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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.
 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.
 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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