



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	195789	METAGENICS MITO ACTIVATE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	16/03/2012	
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 . METAGENICS MITO ACTIVATE

Product Type	Single Medicine Product	Effective Date	10/02/2021
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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 energy production
- Traditionally used in South American medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Traditionally used in South American medicine to decrease/reduce mental/cognitive fatigue

Indication Requirements

- 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.
- Adults only.
- Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.
- If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information



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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	300 mg
Camellia sinensis leaf Extract dry concentrate standardised	400 mg
Equivalent: Camellia sinensis (Dry)	10 g
Ilex paraguariensis leaf Extract dry concentrate	100 mg
Equivalent: Ilex paraguariensis (Dry)	3 g
Panax ginseng root Extract dry concentrate	200 mg
Equivalent: Panax ginseng (Dry)	2 g

Other Ingredients (Excipients)

colloidal anhydrous silica
croscarmellose sodium
hypolose
macrogol 8000
magnesium stearate
microcrystalline cellulose
silicon dioxide
stearic acid

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