



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	195789	METAGENICS MITO ACTIVATE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	16/03/2012	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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

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.

#### 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



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

**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**

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