### **Australian Government**

# Department of Health, Disability and Ageing

Therapeutic Goods Administration

## **Public Summary**

Summary for ARTG Entry: 333163 METAGENICS CELL PROTECT

ARTG entry for Medicine Listed

Sponsor Metagenics (Aust) Pty Ltd

Postal Address PO Box 675, VIRGINIA BC, QLD, 4014

Australia

ARTG Start Date 2/04/2020
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. METAGENICS CELL PROTECT

Product Type Single Medicine Product Effective Date 19/09/2025

# Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support natural body cleansing/detoxification processes

Maintain/support healthy immune system function

# **Indication Requirements**

Product presentation must not imply or refer to serious immunological diseases.

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 only refer to detoxification in relation to natural body processes.

# Standard Indications

No Standard Indications included on Record

# **Specific Indications**

No Specific Indications included on Record

# Warnings

To be taken with food.

In rare cases, Camellia sinensis may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes, or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.

In very rare cases, Curcuma species may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine, or itching.

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.

Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

Adults only.

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.

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

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WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (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

### **Additional Product information**

### Pack Size/Poison information

Pack Size Poison Schedule

### Components

### 1. Formulation 1

Tablet, film coated Dosage Form

**Route of Administration** 

Oral

#### Visual Identification

# **Active Ingredients**

200 mg Camellia sinensis leaf Extract dry concentrate Equivalent: Camellia sinensis (Dry) 5 g .0125 mg Curcuma longa rhizome Extract dry concentrate 76 mg 1.9 g

Equivalent: Curcuma longa (Dry)

molybdenum trioxide Equivalent: molybdenum

Panax ginseng root Extract dry concentrate

Equivalent: Panax ginseng (Dry) 500 mg phytomenadione 2.5 mg Reynoutria japonica root Extract dry concentrate standardised 125 mg Equivalent: Reynoutria japonica (Dry) 12.5 g

187.5 microgram selenomethionine Equivalent: selenium 75 microgram zinc sulfate monohydrate 41.16 mg Equivalent: zinc 15 mg

# Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

croscarmellose sodium

dl-alpha-tocopherol

glycerol

hypromellose

magnesium stearate

maize starch

medium chain triglycerides

microcrystalline cellulose

silicon dioxide

sodium starch glycollate type A

sucrose

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94 microgram

50 mg

62.5 microgram