



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	244880	METAGENICS OXIDANT PROTECTION
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	29/06/2015	
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 OXIDANT PROTECTION

Product Type	Single Medicine Product	Effective Date	17/06/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Helps enhance/promote general health and wellbeing
Maintain/support general health and wellbeing
Maintain/support general health and wellbeing in aging individuals
Maintain/support cardiovascular system health

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	250.04 mg
d-alpha-tocopheryl acid succinate	82.64 mg
Equivalent: d-alpha-tocopherol	100 IU
Reynoutria japonica root Extract dry concentrate standardised	90 mg
Equivalent: Reynoutria japonica (Dry)	9000 mg
selenomethionine	62.1 microgram
Equivalent: selenium	25 microgram
Vitis vinifera seed Extract dry concentrate standardised	100 mg
Equivalent: Vitis vinifera ()	12000 mg
zinc amino acid chelate	80 mg
Equivalent: zinc	16 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
calcium hydrogen phosphate
Carnauba Wax
chlorophyllin-copper complex
citric acid
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
Soya Oil

© 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