



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	256752	METAGENICS E500 TOCOPHEROLS PLUS SELENIUM
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	21/08/2015	
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 E500 TOCOPHEROLS PLUS SELENIUM

Product Type	Single Medicine Product	Effective Date	12/09/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps enhance/promote general health and wellbeing
Maintain/support general health and wellbeing
Helps enhance/promote healthy blood circulation
Helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet)
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support blood capillary health
Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.
Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
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

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

Additional Product information



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Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	
Active Ingredients	
d-alpha-tocopherol	273.1 mg
Equivalent: d-alpha-tocopherol	407 IU
mixed (high-alpha type) tocopherols concentrate	78.0864 mg
selenomethionine	62.5 microgram
Equivalent: selenium	25 microgram
Other Ingredients (Excipients)	
Coconut Oil	
Colour	
Gelatin	
glycerol	
lecithin	
purified water	
Soya Oil	
yellow beeswax	

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