



Australian Government
Department of Health
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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	24/02/2020
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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 circulatory disorders/diseases/conditions e.g. thrombosis.
- Product presentation must not imply or refer to serious cardiovascular 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

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).
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



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exceeded.

Additional Product information

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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