Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 310593 Natural Vitamin E 500IU

ARTG entry for Medicine Listed

Sponsor Herbs of Gold Pty Ltd

Postal Address Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020

Australia

ARTG Start Date 22/10/2018
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 . Natural Vitamin E 500IU

Product Type Single Medicine Product Effective Date 24/09/2025

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support general health and wellbeing

Maintain/support cardiovascular system health

Maintain/support immune system health

Maintain/support healthy immune system function

Decrease/reduce/relieve menstruation pain/dysmenorrhoea

Maintain/support sperm health

Maintain/support sperm motility

Decrease/reduce/relieve itchy/prickling skin associated with mild eczema/dermatitis

Decrease/reduce/relieve symptoms of mild eczema/dermatitis

Maintain/support skin health

Indication Requirements

Product presentation must only refer to mild eczema.

Product presentation must not imply or refer to infertility.

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

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

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

No Warnings included on Record

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 335.58 mg

Other Ingredients (Excipients)

glycerol

hydroxypropyl starch

purified water

Soya Oil

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