

Public Summary

Summary for ARTG Entry: 190425 PSC 1500

ARTG entry for Medicine Listed
Sponsor Tirsell Pty Ltd
Postal Address PO Box 1430, FRANKSTON, VIC, 3199
 Australia
ARTG Start Date 11/10/2011
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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. PSC 1500

Product Type	Single Medicine Product	Effective date	11/10/2011
--------------	-------------------------	----------------	------------

Warnings

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life

For vitamin (may state the vitamin) supplementation.

Specific Indications

- * Antioxidant, or free radical scavenger.
- * Vitamin E protects the cells in the body from oxidative damage by destroying or neutralising free radicals.
- * Vitamin E is an important nutritional antioxidant, which inhibits the oxidization of fats/ lipids in the body/cell membranes.
- * Vitamin E is an important lipid phase nutritional antioxidant, and therefore assists in protecting the body from free radicals that may be generated from exposure to pollution, cigarettes, alcohol and stress.
- * Helps protects cells from free radical damage.
- * Vitamin E is a fat-soluble antioxidant vitamin that helps protect the cell membranes from damage.
- * As an antioxidant vitamin E acts as a 'free-radical scavenger'.
- * Maintains a healthy heart.
- * Supports healthy heart function.
- * Assists in the maintenance of a healthy cardiovascular system.
- * Supports cardiovascular health.
- * Helps maintain healthy blood vessels.
- * Maintains the health of the veins and capillaries.
- * Vitamin E helps maintain heart health and help to support/maintain the health of the artery walls.
- * Vitamin E supports healthy immune function.
- * Supports a healthy immune system.
- * Vitamin E is necessary for healthy immune function.
- * Vitamin D supports the health and function of the immune system.
- * The antioxidant activity of vitamin E may assist in protecting the structures of the eyes from free radical damage.
- * Supports the health of the eyes.
- * Helps to maintain the integrity of cell membranes.

- * The antioxidant activity of vitamin E assists in protecting the polyunsaturated fatty acids in the cell membranes, and other critical cellular structures from lipid peroxidation, or free radical damage.
- * Vitamin E is incorporated into the cell membranes and helps maintain their integrity throughout the body.
- * Assists in the maintenance of healthy male reproductive function.
- * Supports the health and function of the male reproductive system.
- * Contains natural vitamin E, which has been shown to have a higher bioavailability than synthetic vitamin E.
- * Some research indicates that natural vitamin E has approximately twice the bioavailability of synthetic vitamin E.
- * Vitamin D is important for bone health.
- * Vitamin D helps to maintain serum calcium and phosphorus levels, which is critical for the normal development of bones and teeth.
- * Supports the development and maintenance of strong, healthy bones.
- * Supports healthy bone mineral density.
- * Vitamin D supports/helps maintain bone mineral density and helps to reduce the risk of fracture.
- * Vitamin D plays a role in the maintenance of healthy blood sugar levels in healthy people.
- * Vitamin D is mainly produced in our skin by a reaction that requires sunlight. People who limit their exposure to sunlight may have an increased need for vitamin D supplementation.
- * Supports the health and function of the nervous system.
- * Supports neuromuscular function.
- * Assists in the maintenance/supports healthy skin.
- * Supports healthy skin renewal processes.
- * Contains nutrients that are required for the proper integrity of the skin.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
Components	
1. Formulation 1	
Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Albizia lebbbeck	50 mg
Equivalent: Albizia lebbbeck (Dry)	400 mg
Cholecalciferol	.025 mg
d-alpha-Tocopheryl acid succinate	82.65 mg
Glycyrrhiza glabra	10 mg
Equivalent: Glycyrrhiza glabra (Dry)	50 mg
Paeonia lactiflora	14.29 mg
Equivalent: Paeonia lactiflora (Dry)	100 mg
Perilla frutescens	33.34 mg
Equivalent: Perilla frutescens (Dry)	500.1 mg
Poria cocos	3 mg
Equivalent: Poria cocos (Dry)	15 mg
Quercetin	500 mg
Saposhnikovia divaricata	3.75 mg
Equivalent: Saposhnikovia divaricata (Dry)	15 mg
Scutellaria baicalensis	3.75 mg
Equivalent: Scutellaria baicalensis (Dry)	15 mg

© 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>.