

Public Summary

Summary for ARTG Entry: 230910 PSC 100

ARTG entry for Medicine Listed
Sponsor Tirsell Pty Ltd
Postal Address PO Box 1430, FRANKSTON, VIC, 3199
 Australia
ARTG Start Date 21/11/2014
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 100

Product Type	Single Medicine Product	Effective date	21/11/2014
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Warnings

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

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

Phenylketonurics are warned that this product contains phenylalanine (or words to that effect).

This product 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.

Standard Indications

- Helps relieve nervous unrest. [Warning S required]
- Helps relieve nervous tension, stress and mild anxiety. [Warning S required]
- For the relief of irritability. [Warning S required]
- Beneficial during times of stress. [Warning S required]
- Aids, assists or helps in the maintenance of general well-being
- Help reduce effects of mild anxiety and nervous tension. [Warning S required]

Specific Indications

- Supports the health of the skin.
- Helps to maintain healthy skin.
- Supports healthy skin regenerative processes.
- Supports skin renewal and wound healing.
- Helps to maintain healthy skin function and repair.
- Supports the body's natural anti-inflammatory processes.
- Contains antioxidant nutrients and therefore may assist in protecting the cells in the body from oxidative damage.
- Contains nutrients that play a role in the body's antioxidant systems.
- Assists in protecting cells and tissues from free radical damage.
- Selenium is an important part of the enzyme glutathione peroxidase, and therefore is involved in the body's antioxidant systems.
- Selenium is a necessary component of the enzyme glutathione peroxidase, which neutralises free radicals.
- Maintains healthy immune function.
- Selenium supports the health and function of the immune system.

Supports healthy immune function.
 Supports the health of the liver and assists in protecting the liver from potential oxidative damage.
 Maintains/supports the health of the liver.

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

Boswellia serrata

50 mg

Equivalent: Boswellia serrata (Dry)

200 mg

calcium ascorbate dihydrate

12.5 mg

Chondroitin sulfate - bovine

80 mg

Curcuma longa

62.5 mg

d-alpha-Tocopheryl acid succinate

10.35 mg

Dimethyl sulfone

300 mg

Glucosamine hydrochloride

150 mg

Glutamine

25 mg

Inositol

25 mg

Magnesium oxide - heavy

22.3 mg

Manganese amino acid chelate

750 microgram

Nicotinamide

50 mg

Phenylalanine

75 mg

Selenomethionine

375 microgram

Smilax officinalis

50 mg

Equivalent: Smilax officinalis (Dry)

200 mg

Taurine

25 mg

Zinc oxide

8.9 mg

Zingiber officinale

9.09 mg

Equivalent: Zingiber officinale (Dry)

100 mg

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