

Public Summary

Summary for ARTG Entry: 141856 Dr Michael's PSC 300

ARTG entry for	Medicine Listed
Sponsor	Tirsel Pty Ltd
Postal Address	PO Box 1430, FRANKSTON, VIC, 3199 Australia
ARTG Start Date	9/07/2007
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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27). This condition does not apply to powdered or dried leaf.

Products

1. Dr Michael's PSC 300

Product Type	Single Medicine Product	Effective date	9/07/2007
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Warnings

For practitioner dispensing only.

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.

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

Standard Indications

May assist in the management of dry skin.

For the symptomatic relief of dry skin.

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

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

Specific Indications

No Specific Indications included on Record

Additional Product information

Pack Size/Poison information

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

Visual Identification

Active Ingredients

Betacarotene	1.3995 mg
Bupleurum falcatum	4.5 mg
Equivalent: Bupleurum falcatum (Dry)	45 mg
Cholecalciferol	.0025 mg
Chromic chloride	154 microgram
Copper gluconate	714 microgram
Gentiana lutea	
Ginkgo biloba	10 mg
Equivalent: Ginkgo biloba (Dry)	500 mg
Glycine	30 mg
Glycyrrhiza glabra	25 mg
Equivalent: Glycyrrhiza glabra (Dry)	100 mg
Magnesium oxide - heavy	189 mg
Magnesium phosphate	25.2 mg
Manganese amino acid chelate	20 mg
Matricaria chamomilla	9.37 mg
Equivalent: Matricaria chamomilla (Dry)	37.5 mg
Oligofructose	50 mg
Plantago asiatica	20 mg
Equivalent: Plantago asiatica (Dry)	100 mg
Potassium iodide	131 microgram
Potassium phosphate - monobasic	25 mg
Potassium sulfate	33.4 mg
Scutellaria baicalensis	11.25 mg
Equivalent: Scutellaria baicalensis (Dry)	45 mg
Selenomethionine	62.5 microgram
Vitis vinifera	1 mg
Zinc amino acid chelate	62.5 mg

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