

Public Summary

Summary for ARTG Entry: 142597 Dr Michaels PSC 900

ARTG entry for Medicine Listed
Sponsor Tirsell Pty Ltd
Postal Address PO Box 1430, FRANKSTON, VIC, 3199
 Australia
ARTG Start Date 27/07/2007
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.

Products

1. Dr Michaels PSC 900

Product Type	Single Medicine Product	Effective date	27/07/2007
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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 the medicine contains one sorbate) Contains [insert name of sorbate] OR (if medicine contains two or more sorbates) Contains sorbates [or words to that effect].

(If medicine contains one benzoate) Contains [insert name of benzoate] Or (If medicine contains two or more benzoates) Contains benzoates [or words to that effect].

For practitioner dispensing only.

Standard Indications

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

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

May assist in the management of dry skin.

For the symptomatic relief of dry skin.

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	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

Calcium gluconate	32.5 mg/mL
ferrous gluconate dihydrate	20 mg/mL
Folic acid	250 microgram/mL
Magnesium chloride	20.75 mg/mL
Potassium gluconate	50 mg/mL
Pyridoxine hydrochloride	2.5 mg/mL
Zinc sulfate monohydrate	30.91 mg/mL

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