

Public Summary

Summary for ARTG Entry: 104312 Dr Michaels Scalp and Body Skin Conditioner

ARTG entry for	Medicine Listed
Sponsor	Tirsel Pty Ltd
Postal Address	PO Box 1430, FRANKSTON, VIC, 3199 Australia
ARTG Start Date	30/06/2004
Product category	Medicine
Status	Active
Approval area	Listed Medicines

Conditions

Sponsors of products that contain Emu Oil must ensure that the emu oil ingredient meets the following two requirements: firstly, the manufacturing process is to include steps such as cooking, fat drying or deodorising which ensures the temperature of the oil reaches at least 60 degrees C for a minimum 5 minutes or at least 100 degrees C for a minimum of 1 minute, and secondly, the sponsor is to hold a veterinary certificate indicating that the emus from which the raw material was extracted were healthy and fit for human consumption..

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 Scalp and Body Skin Conditioner

Product Type	Single Medicine Product	Effective date	30/06/2004
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Warnings

Contains Citronella Oil (or words to that effect).

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

Standard Indications

Treatment of minor skin disorders such as wounds, scratches, eczema, dermatitis, bruising, cuts and abrasions. [Warning S required]

For the symptomatic relief of psoriasis. [Warning S required]

For the symptomatic relief of dermatitis. [Warning S required]

For the symptomatic relief of dry skin.

For the symptomatic relief of mild to moderate acne.

For the symptomatic relief of urticaria. [Warning S required]

May assist in the management of eczema. [Warning S required]

Treatment of dry or inflamed skin conditions. [Warning S required]

Treatment of acne. [Warning S required]

May assist in the management of mild to moderate acne.

May assist in the management of dry skin.

May assist in the management of dermatitis. [Warning S required]

May assist in the management of psoriasis. [Warning S required]

For the symptomatic relief of eczema. [Warning S required]

Treatment of the effects of psoriasis on the skin. [Warning S required]

Relief of the effects of psoriasis on the skin. [Warning S required]

Relief of the symptoms of eczema. [Warning S required]

Specific Indications

Recent clinical trials undertaken in Semmelweis Hospital Budapest and AKH Hospital Vienna have shown that there are triggers [provoking factors] that flare up and/or continue to exacerbate Psoriasis and Eczema. These triggers include: 1. Large daily intake of acidic foods and/or diuretics. 2. Chemicals- Smoking and exposure to paints, insecticides and pesticides and some drug interaction. 3. Anxiety, stress and worry. 4. Inadequate supply of green vegetables. It is for this reason that we have developed formulations to try and combat the effects of these triggers.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
Components	
1. Medicine Component	
Dosage Form	Lotion
Route of Administration	Topical
Visual Identification	
Active Ingredients	
Calendula officinalis	10 mg/mL
Equivalent: Calendula officinalis (Dry)	2.28 mg/mL
Emu oil	8 mg/mL
Wheatgerm Oil	15 mg/mL

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