

Public Summary

Summary for ARTG Entry: 109214 DR MICHAELS SCALP AND BODY CLEANSING GEL.

ARTG entry for Medicine Listed (Export Only)
Sponsor Tirsell Pty Ltd
Postal Address PO Box 1430, FRANKSTON, VIC, 3199
 Australia
ARTG Start Date 20/09/2004
Product category Medicine
Status Active
Approval area Export only Medicines

Conditions

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions. The sponsor will provide stability data to the Head, Medicines Authorisation Branch, TGA upon request, except where the overseas importer accepts responsibility for stability studies. When an overseas importer accepts responsibility for providing stability data for this product, it is the sponsor's responsibility to ensure that they have a written agreement to this effect from the overseas importer. The sponsor will provide a copy of this agreement to the Head, Medicines Authorisation Branch, TGA upon request.

Products

1. DR MICHAELS SCALP AND BODY CLEANSING GEL.

Product Type	Single Medicine Product	Effective date	20/09/2004
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Warnings

No Warnings included on Record

Standard Indications

May assist in the management of urticaria. [Warning S required]
 Relief of the symptoms of eczema. [Warning S required]
 Relief of the effects of psoriasis on the skin. [Warning S required]
 Treatment of the effects of psoriasis on the skin. [Warning S required]
 Treatment of effects of psoriasis. [Warning S required]
 For the symptomatic relief of eczema. [Warning S required]
 May assist in the management of psoriasis. [Warning S required]
 May assist in the management of dermatitis. [Warning S required]
 May assist in the management of eczema. [Warning S required]
 For the symptomatic relief of urticaria. [Warning S required]
 For the symptomatic relief of mild to moderate acne.
 For the symptomatic relief of dry skin.
 For the symptomatic relief of dermatitis. [Warning S required]
 For the symptomatic relief of psoriasis. [Warning S required]
 Treatment of minor skin disorders such as wounds, scratches, eczema, dermatitis, bruising, cuts and abrasions. [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.

Specific Indications

No Specific Indications included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
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Bottle Not recorded Not recorded Store below 30 degrees Celsius Not recorded Not recorded

Pack Size/Poison information

Pack Size

Not Required

Components

1. SOLUTION GEL

Dosage Form

Route of Administration

Visual Identification

Active Ingredients

Citrus bioflavonoids extract

Coal tar

Salicylic acid

Poison Schedule

Not scheduled. Not considered by committee

Gel

Topical

20 mg/mL

15 mg/mL

25 mg/mL

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