

COMPLEMENTARY MEDICINE

This unregistered medicine has not been evaluated by the SAHPRA for its quality safety or intended use.

SCHEDULING STATUS: **SO**

PROPRIETARY NAME AND DOSAGE FORM
DERMIKELP® ITCH RELIEF SHAMPOO

COMPOSITION

Active ingredient:

Each ml contains 135 mg of *Ecklonia maxima* (Sea Kelp).

Inactive ingredients:

Water (aqua), sodium lauryl sulphate, cocamide DEA, sodium benzoate, polyquaternium 10, potassium sorbate, parfum, polysorbate 20, triethanolamine 99%, gluconolactone, caprylic glycerol and phenoxyethanol, acrylates/C10-30 alkyl acrylate crosspolymer and citric acid.

PHARMACOLOGICAL CLASSIFICATION

D 33.8 Complementary medicines: Discipline-specific traditional claims – Other

PHARMACOLOGICAL ACTION

Pharmacodynamic properties:

Ecklonia maxima is a member of the genus *Ecklonia* and contains a variety of compounds that play diverse biological and ecological roles. The isolates from *Ecklonia maxima* are phloroglucinol, eckol, 7-phloroeckol and 2-phloroeckol.

Pharmacokinetic properties:

Ecklonia species are utilized for therapeutic applications as they exhibit antioxidant and anti-inflammatory activities.

INDICATIONS

DERMIKELP® ITCH RELIEF SHAMPOO assists with the symptoms associated with dry, itchy or irritated scalp.

CONTRAINDICATIONS

Hypersensitivity to *Ecklonia maxima*, iodine or any of the other ingredients (see COMPOSITION).

WARNINGS AND SPECIAL PRECAUTIONS

A temporary stinging or burning sensation may be felt when applied to broken skin.

Effects on ability to drive and use machines:

No studies have been done to establish the effects on the ability to drive a vehicle or operate machinery.

INTERACTIONS

Do not use in combination with other topical applications unless otherwise indicated by a health care professional.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

For external use only.

Wet hair and apply **DERMIKELP® ITCH RELIEF SHAMPOO** and gently massage into the scalp. Rinse and repeat as required.

SIDE EFFECTS

Skin and subcutaneous tissue disorders:

Less frequent: Light erythema.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT

DERMIKELP® ITCH RELIEF SHAMPOO is indicated for external use only. In the event of accidental ingestion, treatment should be symptomatic and supportive.

IDENTIFICATION

A beige to light brown shampoo with characteristic odour.

PRESENTATION

White, plastic bottle packed into an outer carton.

Pack size: 100 ml and 200 ml.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from sunlight.

Keep bottle closed.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

To be allocated by the SAHPRA

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Lamicare SA (Pty) Ltd t/a Lamicare Health

Registration no: 2008/024158/07

Unit A2, Arden Grove Business Park

Racecourse Road

Milnerton

7441

Tel: 086 100 0400

DATE OF PUBLICATION OF PACKAGE INSERT

September 2020

KOMPLEMENTÈRE MEDISYNE

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA vir kwaliteit, veiligheid of beoogde gebruik geëvalueer nie.

SKEDULERINGSTATUS: **SO**

EIENDOMSNAAM EN DOSEERVORM
DERMIKELP® JEUKVERLIGTENDE SJAMPOE

SAMESTELLING

Aktiewe bestanddeel:

Elke ml bevat 135 mg *Ecklonia maxima* (Seewier).

Onaktiewe bestanddele:

Water, natriumlaureletersulfaat, kokamied DEA, natriumbensoaat, polikwaternium-10, kaliumsorbat, parfum, polysorbat 20, triethanolamien 99%, gluconolaktoon, kaprilieglolikol, fenoksietanol, alkilate/C10-30 alkielakrilaat kruispolimeer en stroensuur.

FARMAKOLOGIESE KLASIFIKASIE

D 33.8 Komplementêre medisyne: Middels met dissipline-spesifieke tradisionele aansprake - Ander kruiemiddels

FARMAKOLOGIESE WERKING

Farmakodinamiese eienskappe:

Ecklonia maxima is 'n lid van die *Ecklonia* genus en bevat 'n verskeidenheid verbindings wat diverse biologiese en ekologiese rol speel.

Floroglusinol, ekkol, 7-floroekkol en 2-floroekkol word uit *Ecklonia maxima* geïsoleer.

Farmakokinetiese eienskappe:

Die genus *Ecklonia* word vir terapeutiese toedienings benut, aangesien dit antioksidant en anti-inflammatoriese werking toon.

INDIKASIES

DERMIKELP® JEUKVERLIGTENDE SJAMPOE help om die simptome wat geassosieer word met droë, jeukende of geirriteerde kopvel te verlig.

KONTRA-INDIKASIES

Hipersensitiviteit vir *Ecklonia maxima*, jodium of enige van die ander bestanddele in **DERMIKELP® JEUKVERLIGTENDE SJAMPOE** (kyk SAMESTELLING).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREELS

'n tydelik steeksensasie mag gevloof word wanneer dit aan stukkende vel aangewend word.

Effek op die vermoë om te bestuur en masjinerie te gebruik:

Daar is geen studies uitgevoer om die effek op die vermoë om 'n voertuig te bestuur of masjinerie te hanteer, te bepaal nie.

INTERAKSIES

Moet nie in kombinasie met ander topikale produkte toedien nie, behalwe indien anders aangedui deur 'n gesondheidsorgdeskundige.

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

DOSIS EN GEBRUIKSAANWYSINGS

Slegs vir uitwendige gebruik.

Maak haré hat en wend **DERMIKELP® JEUKVERLIGTENDE SJAMPOE** aan. Masser liggies in die kopvel in. Spoel af en herhaal soos nodig.

NEWE-EFFEKTE

Vel-en subkutaneweefselversteurings:

Minder dikwels: Ligte eritem.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

DERMIKELP® JEUKVERLIGTENDE SJAMPOE is slegs vir uitwendige gebruik aangedui. In die geval van toevallige inname, moet behandeling simptomaties en ondersteunend wees.

IDENTIFIKASIE

'n Beige tot ligbruin sjampee met 'n kenwerkende geur.

AANBIEDING

Wit plastiekbottel verpak in 'n buitenste karton.

Verpakkingsgrootte: 100 ml en 200 ml

BEWARINGSINSTRUKSIES

Bére by of onder 25 °C.

Beskerm teen direkte sonlig.

Hou bottel dig toe.

HOU BIJTE BEREIK VAN KINDERS.

REGISTRASIONOMMER

Sal deur die SAHPRA toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

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DATUM VAN PUBLIKASIE VAN DIE VOUBILJET

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