

COMPLEMENTARY MEDICINE

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

SCHEDULING STATUS:**S0**

PROPRIETARY NAME AND DOSAGE FORM
DERMIKELP® BODY WASH

COMPOSITION

Active ingredient:

Each ml contains 97,5 mg of *Ecklonia maxima* (Sea Kelp).

Inactive ingredients:

Water (aqua), sodium lauryl ether sulfate, cocamidopropyl betaine, triethanolamine, citric acid, sodium benzoate, methylisothiazolinone and decylene glycol, acrylates C10-30 alkyl acrylate crosspolymer, polysorbate-20, parfum, ethylene/sodium acrylate crosspolymer, gluconolactone, caprylyl glycol and phenoxyethanol.

PHARMACOLOGICAL CLASSIFICATION

D33.8 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 utilised for therapeutic applications as they exhibit antioxidant and anti-inflammatory activities.

INDICATIONS

DERMIKELP® BODY WASH assists with the symptoms associated with eczema, psoriasis and dermatitis.

CONTRAINDICATIONS

Hypersensitivity to *Ecklonia maxima*, iodine or any of the other ingredients in **DERMIKELP® BODY WASH** (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 healthcare professional.

PREGNANCY AND LACTATION

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

For external use only.

Squeeze a generous amount onto a washcloth, sponge or palm of hand and lather over the body. Rinse well. Can be used daily to clean and soothe irritated and itchy skin. If **DERMIKELP® BODY WASH** gets into the eyes, wash thoroughly with water.

SIDE EFFECTS

Skin and subcutaneous tissue disorders:

Less frequent: Light erythema.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT

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

IDENTIFICATION

A beige to light brown body wash with characteristic odour.

PRESENTATION

White plastic container with a Disc cap or flip top cap, packed into a printed outer carton. Packing size 100 ml and 200 ml.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from sunlight.

Keep container 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 THE PACKAGE INSERT

September 2020

KOMPLEMENTÈRE MEDISYNE

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

SKEDULERINGSTATUS:**S0**

EIENDOMSNAAM EN DOSEERVORM
DERMIKELP® LYFWASMIDDEL



SAMESTELLING

Aktiewe bestanddeel:

Elke ml bevat 97,5 mg *Ecklonia maxima* (Seewier).

Onaktiewe bestanddele:

Water, natriumlaurylethersulfaat, kokamidopropielbetaïen, triëtanolamien, sitroensuur, natriumbensoaat, metielisositolinoon, desleenglikol, akrilate/C10-30 alkielakrilaat, kaprilpolimiere, polisorbaat-20, parfum etheleen/natriumakraatkruispolymer, glukonolaktoon, kapriielglikol en fenoksiëtanol.

FARMAKOLOGIESE KLASSIFIKASIE

D32.16 Ander

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 antioksident en anti-inflammatoriese werking toon.

INDIKASIES

DERMIKELP® LYFWASMIDDEL help met die simptome wat verband hou met eksem, psoriasis en dermatitis.

KONTRA-INDIKASIES

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

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Wanneer dit aangewend word, mag 'n steek- of brandsensasie gevoel 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 hanter, 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.

Druk 'n ruim hoeveelheid op 'n waslap, spons of palm van die hand en vryf tot dit skuum oor die liggaam. Spoel goed af. Kan daagliks gebruik word om geirriteerde en jeukende vel te reinig en te streef. Indien **DERMIKELP® LYFWASMIDDEL** in die oë kom, spoel deeglik uit met water.

NEWE-EFFEKTE

Vel- en subkutaneweefselversturings:

Minder dikwels: Ligte eritem.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

DERMIKELP® LYFWASMIDDEL word slegs vir uitwendige gebruik aangedui. In die geval van toevallige innname, moet behandeling simptomatis en ondersteunend wees.

IDENTIFIKASIE

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

AANBIEDING

Wit plastiekhouer met 'n skyfdop of flip top deksel, verpak in 'n gedrukte buitenste karton. Verpakkingsgrootte: 100 ml en 200 ml.

BEWAARINGSINSTRUKSIES

Bêre by of onder 25 °C.

Beskerm teen direkte sonlig.

Hou die houer dig toe.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER

Sal deur die SAHPRA toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Lamicare SA (Pty) Ltd t/a Lamicare Health

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DATUM VAN PUBLIKASIE VAN DIE VOUBILJET

September 2020