

COMPLEMENTARY MEDICINE

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

SCHEDULING STATUS: S0

PROPRIETARY AND DOSAGE FORM
DERMIKELP® ITCH RELIEF LOTION

COMPOSITION

Active ingredient:

Each ml contains 375 mg of *Ecklonia maxima* (sea kelp)

Inactive ingredients:

Aqua, benzyl benzoate, caprylyl glycol, *Cananga odorata* (ylang-ylang) flower oil, cetearyl alcohol, cetearyl glucoside, citric acid, ethylhexylglycerin, gluconolactone, isopropyl myristate, linalool, paraffinum liquidum, PEG-20 stearate, phenoxyethanol, sodium benzoate.

PHARMACOLOGICAL CLASSIFICATION

D33.8 Complementary medicines: Discipline-specific traditional claims – Other herbal

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-phloroecol and 2-phloroecol.

Pharmacokinetic properties

Ecklonia species are utilised for therapeutic applications as they exhibit antioxidant and anti-inflammatory activities. Fucoidans in *Ecklonia maxima* reduce IgE production as well as the number of IgE-secreting cells in peripheral blood mononuclear cells (PBMC), without affecting cell proliferation and interferon- γ production. Fucoidans suppress IgE induction by inhibiting immunoglobulin class-switching to IgE in human B cells. Polyphenolic substance from phlorotannins exhibit the potential anti-allergic mechanism by the suppression of the binding activity between IgE and Fc ϵ RI in *vitro*. The anti-inflammatory properties of phlorotannins are related to the down-regulation of iNOS, COX-2 and proinflammatory cytokines through the negative regulation of the NF κ B pathway.

INDICATIONS

DERMIKELP® ITCH RELIEF LOTION soothes itchy irritated skin and is suitable for the symptoms associated with eczema, contact dermatitis, seborrhoeic dermatitis, minor insect bites and allergic skin reactions caused by soaps, detergents, cosmetics and jewellery. Suitable for the blending of dermatological preparations.

CONTRAINDICATIONS

Hypersensitivity to *Ecklonia maxima*, iodine or any of the other ingredients in **DERMIKELP® ITCH RELIEF LOTION** (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

Apply to the affected area as required. Massage gently into the skin to ensure proper absorption. Can be used daily as required.

SIDE EFFECTS

See **WARNINGS AND SPECIAL PRECAUTIONS**.

Skin and subcutaneous tissue disorders:

Less frequent: Light erythema.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT

External use only. In the event of accidental ingestion, treatment should be symptomatic and supportive.

IDENTIFICATION

Off-white to beige cream with characteristic odour.

PRESENTATION

White, plastic bottle packed into an outside carton.
Pack sizes: 100 ml, 200 ml.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from direct sunlight.

Keep container tightly 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
A2, Arden Grove Business Park
Racecourse Road
Milnerton
7441
Tel: 086 100 0400

DATE OF PUBLICATION OF PACKAGE INSERT

March 2020

KOMPLEMENTÊRE MEDISYNE

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

SKEDULERINGSTATUS: S0

HANDELSNAAM EN DOSEERVORM
DERMIKELP® ITCH RELIEF LOTION

SAMESTELLING

Aktiewe bestanddeel:

Elke ml bevat 375 mg *Ecklonia maxima* (seewier).

Onaktiewe bestanddele:

Water, bensielbensoaat, kapriëgliskol, *Cananga odorata* (ylang-ylang) blomolie, setearielalkohol, setearielglukosied, sitroensuur, etielheksielgliserien, glukonolaktoon, isopropielmiristaat, minerale-olie, PEG-20 stearaat, fenoksiëtanol, natriumbensoaat.

FARMAKOLOGIESE KLASSEKASIE

D33.8 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 bindings- wat diverse biologiese en ekologiese rolle speel. Floroglusinol, ekkol, 7-floroëkkol en 2-floroëkkol word uit *Ecklonia maxima* geïsoleer.

Farmakokinetiese eienskappe

Die genus *Ecklonia* word vir terapeutiese toedienings benut, aangesien dit antioksidant en anti-inflammatoriese werking toon. Fukoidane in *Ecklonia maxima* verminder die produksie van IgE sowel as die aantal selle wat IgE afskei in perifere bloed mononukleêre selle, sonder om proliferasie van selle en produksie van interferon- γ te beïnvloed. Fukoidane onderdruk induksie van IgE deur omskakeling tussen immunoglobulienklasse na IgE in mens B-selle te onderdruk. Polifenoliese bindings- uit florotanniene vertoon die potensieël anti-allergie meganisme deur die bindingsaktiwiteit tussen IgE en Fc ϵ RI in *vitro* te onderdruk.

Die anti-inflammatoriese eienskappe van florotanniene hou verband met die afwaartse regulering van iNOS, COX-2 en proinflammatoriese sitokiene deur die negatiewe regulering van die NF κ B-weg.

INDIKASIE

DERMIKELP® ITCH RELIEF LOTION streef jeukende, geïrriteerde vel en dit is geskik vir die simptome geassosieer met ekseem, kontakdermatitis, seborree-dermatitis, minder ernstige insekbyte en allergiese velreaksies veroorsaak deur sepe, skoonmaakmiddels, grimering en juweliersware. Geskik vir die vermening van dermatologiese produkte.

KONTRA-INDIKASIE

Hipersensitieweit vir *Ecklonia maxima*, jodium of enige van die ander bestanddele in **DERMIKELP® ITCH RELIEF LOTION** (kyk **SAMESTELLING**).

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

'n Tydelik steeksensasie mag gevoel word wanneer **DERMIKELP® ITCH RELIEF LOTION** 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.

INTERAKSIE

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.

Wend aan die aangetaste oppervlak, soos nodig. Masseer sagkens in die vel in, om te verseker dat dit voldoende geabsorbeer word.
Kan daagliks gebruik word, soos nodig.

NEWE-EFFEKTE

Kyk **WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS**.

Vel- en subkutaneweeffselversteurings:

Minder dikwels: Ligte erteem.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

Slegs vir uitwendige gebruik aangedui. In die geval van toevallige inname, moet behandeling simptome en ondersteunend wees.

IDENTIFIKASIE

Naaswit tot beige room met kenmerkende geur.

AANBIEDING

Wit plastiek bottel bottle in 'n buitenste karton.

Verpakkings groottes: 100 ml, 200 ml.

BEWARINGSINSTRUKSIES

Bêre by of onder 25 °C.

Beskerm teen direkte sonlig.

Hou bottel 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
A2, Arden Grove Business Park
Racecourse Road
Milnerton
7441
Tel: 086 100 0400

DATUM VAN PUBLIKASIE VAN DIE VOUILJET

Maart 2020