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® ITCH RELIEF CREAM

COMPOSITION
Active ingredient:
Each gram 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

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. 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-y production. Fucoidans supress IgE induction by inhibiting immunoglobulin class-switching to IgE in human B cells. Polyphenolic substances from phlorotannins exhibit the potential anti-allergic mechanism by the suppression of the binding activity between IgE and FcεRI *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 NFKB pathway.

INDICATIONS
DERMIKELP ITCH RELIEF CREAM 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.

CONTRAINDICATIONS
Hypersensitivity to *Ecklonia maxima*, iodine or any of the other ingredients in **DERMIKELP® ITCH RELIEF CREAM** (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 tube/jar packed into an outside carton.
Pack sizes: 25 g, 50 g, 100 g and 500 g.

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Protect from 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
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7441
Tel: 086 100 0400

DATE OF PUBLICATION OF PACKAGE INSERT
August 2019

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 CREAM – JEUKVERLIGTENDE ROOM

SAMESTELLING
Aktiewe bestanddeel:
Elke gram bevat 375 mg *Ecklonia maxima* (seewier)
Onaktiewe bestanddele:

Bensielbensoaat, *Cananga odorata* (ylang-ylang) blomolie, etielheksielgliserien, fenoksiëtanol, glukonolaktoon, isopropielmiristaat, kaprilielglikol, linalool, mineraalolie, natriumbensoaat, PEG-20 stearaat, setearielalkohol, setearielglukosied, sitroensuur, water.

FARMAKOLOGIESE KLASSIFIKASIE
D33.8 Komplementêre medisyne: Middels met dissipline-spesifieke tradisionele aansprake - Ander

FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Ecklonia maxima is 'n lid van die *Ecklonia* genus en bevat 'n verskeidenheid verbindings 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. Fukoïdane 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-y te beïnvloed. Fukoïdane onderdruk induksie van IgE deur omskakeling tussen immunoglobulienklasse na IgE in mens B-selle te onderdruk. Polifenoliese verbindings uit florotanniene vertoon die potensiële anti-allergie meganisme deur die bindingsaktiwiteit tussen IgE en FcεRI *in vitro* te onderdruk.
Die anti-inflammatoriese eienskappe van florotanniene hou verband met die afwaartse regulering van iNOS, COX-2 en proïnflammatoriese sitokiene deur die negatiewe regulering van die NFKB-weg.

INDIKASIES
DERMIKELP® ITCH RELIEF CREAM streel 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.

KONTRA-INDIKASIES
Hipersensitiwiteit vir *Ecklonia maxima*, jodium of enige van die ander bestanddele in **DERMIKELP® ITCH RELIEF CREAM** (kyk **SAMESTELLING**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
'n Tydelik steeksensasie mag gevoel word wanneer **DERMIKELP® ITCH RELIEF CREAM** 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.
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 VOORSORGMAATREËLS**.
Vel- en subkutaneweefselversteurings:
Minder dikwels: Ligte eriteem.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Slegs vir uitwendige gebruik aangedui. In die geval van toevallige inname, moet behandeling simptomaties en ondersteunend wees.

IDENTIFIKASIE
Naaswit tot beige room met kenmerkende geur.

AANBIEDING
Wit plastiekbuis/potjie verpak in 'n buitenste karton.
Verpakkingsgroottes: 25 g, 50 g, 100 g en 500 g.

BEWARINGSINSTRUKSIES
Bêre by of onder 25 °C.
Beskerm teen direkte sonlig.
Hou buisie/potjie dig toe.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER
Sal deur die SAHPRA toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
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