COMPLEMENTARY MEDICINE

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

SCHEDULING STATUS: S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
DERMIKELP® ITCH RELIEF LOTION

Please read this leaflet carefully because it contains important information for you:
Keep this leaflet. You may need to read it again.
Do not share **DERMIKELP® ITCH RELIEF LOTION** with any other person.
Ask your pharmacist if you need more information or advice.
You must see a doctor if your symptoms worsen or do not improve after ten days.

1. WHAT DERMIKELP® ITCH RELIEF LOTION CONTAINS
Each ml contains 375 mg of *Ecklonia maxima* (Sea kelp) as active ingredient.
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.

2. WHAT DERMIKELP® ITCH RELIEF LOTION IS USED FOR
DERMIKELP® ITCH RELIEF LOTION soothes itchy irritated skin and is suitable for minor insect bites, stings and stinging nettles. It is also suitable for the blending of dermatological preparations (only to be done by your doctor or pharmacist).

3. BEFORE YOU USE DERMIKELP® ITCH RELIEF LOTION
Do not use DERMIKELP® ITCH RELIEF LOTION:
If you are hypersensitive (allergic) to *Ecklonia maxima*, iodine or any of the other ingredients of **DERMIKELP® ITCH RELIEF LOTION** (see **DERMIKELP® ITCH RELIEF LOTION CONTAINS**).
Take special care with DERMIKELP® ITCH RELIEF LOTION:
If you have broken skin areas: **DERMIKELP® ITCH RELIEF LOTION:** can cause a temporary burning or stinging sensation when you apply it to broken skin.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, please consult your doctor, pharmacist or healthcare professional before using **DERMIKELP® ITCH RELIEF LOTION.**
Safety during pregnancy and breastfeeding has not been established.

Drive and using machinery:
No studies have been done to establish the safety of **DERMIKELP® ITCH RELIEF LOTION** during driving a vehicle or operating machinery. Do not drive a vehicle, operate machinery, or do anything else that require your attention until you know how **DERMIKELP® ITCH RELIEF LOTION** affects you.

Using other medicines with DERMIKELP® ITCH RELIEF LOTION:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).
Do not use **DERMIKELP® ITCH RELIEF LOTION** in combination with other topical applications (such as creams or ointments). Unless otherwise indicated by your healthcare professional.

4. HOW TO USE DERMIKELP® ITCH RELIEF LOTION
For external use only.
Always use **DERMIKELP® ITCH RELIEF LOTION** exactly as instructed. You should check with your doctor or pharmacist if you are unsure.
Apply to the affected area as required. Massage gently into your skin to ensure proper absorption.
DERMIKELP® ITCH RELIEF LOTION can be used daily as required.
If you have the impression that the effect of **DERMIKELP® ITCH RELIEF LOTION** is too strong or too weak, talk to your doctor or pharmacist.

If you use more DERMIKELP® ITCH RELIEF LOTION than you should:
If you or your child accidentally ingested **DERMIKELP® ITCH RELIEF LOTION**, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining cream with you so that the doctor will know what you have taken.

If you forget to use DERMIKELP® ITCH RELIEF LOTION:
Apply daily as required.

5. POSSIBLE SIDE EFFECTS
DERMIKELP® ITCH RELIEF LOTION can have side effects.
Not all side effects reported for DERMIKELP® ITCH RELIEF LOTION are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DERMIKELP® ITCH RELIEF LOTION, please contact your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using **DERMIKELP® ITCH RELIEF LOTION** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of your hands, feet ankles, face, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

There are all very series side effects. If you have them, you may have had a serious allergic reaction to **DERMIKELP® ITCH RELIEF LOTION**. You may need urgent medical attention or hospitalisation.
Tell your doctor if you notice any of the following:
- Slight redness of your skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF DERMIKELP® ITCH RELIEF LOTION
- Store at or below 25 °C.
- Keep closed. Protect from sunlight

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Do not use after the expiry date printed on the label or carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains and sewerage systems (e.g toilets).

7. PRESENTATION OF DERMIKELP® ITCH RELIEF LOTION
White, plastic bottle packed into an outside carton.
Pack sizes: 100 ml, 200 ml.

8. IDENTIFICATION OF DERMIKELP® ITCH RELIEF LOTION
Off-white to beige cream with characteristic flavour.

9. REGISTRATION NUMBER
To be allocated by the SAHPRA.

10. NAME AND ADDRESS OF THE REGISTRATION HOLDER
Lamicare SA (Pty) Ltd t/a Lamicare Health
A2, Arden Grove Business Park
Racecourse Road, Milnerton, 7441
Tel: 086 100 0400

11. DATE OF PUBLICATION
March 2020

KOMPLEMENTÊRE MEDISYNE

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

SKEDULERINGSTATUS: S0

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM
DERMIKELP® ITCH RELIEF LOTION

Lees asseblief hierdie hele inligtingsblad noukeurig deur, want dit bevat belangrike inligting vir jou:
Hou hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
Moet nie **DERMIKELP® ITCH RELIEF LOTION** met enige ander persoon deel nie. Vra jou apteker indien jy meer inligting of advies nodig het. Jy moet 'n dokter gaan sien indien jou simptome vererger of nie verbeter na tien dae nie.

1. WAT DERMIKELP® ITCH RELIEF LOTION BEVAT
Elke ml bevat 375 mg *Ecklonia maxima* (seewier) as, aktiewe bestanddeel.
Onaktiewe bestanddele: Water, bensiel bensoaate, kapriliel glikol, *Cananga odorata* (ylang-ylang) blomolief, setearielalk alkohol, setearielg glukosiede, sitroensuur, etielheksielgliserien, glukonolaktoone, isopropie miristaate, linalool, mineraalolie, PEG-20 stearaate, fenoksitanol, natriumbensoaat.

2. WAARVOOR DERMIKELP® ITCH RELIEF LOTION GEBRUIK WORD
DERMIKELP® ITCH RELIEF LOTION streel jeukende, geïrriteerde vel en dit is geskik vir die verligtig van simptome geassosieer met insekbyte, insekteke en brandnetels. Dit is ook geskik vir die vermening van dermatologiese produkte (deur 'n dokter of apteker).

3. VOORDAT JY DERMIKELP® ITCH RELIEF LOTION GEBRUIK
Moet nie DERMIKELP® ITCH RELIEF LOTION gebruik nie:
Indien jy hipersensitief (allergies) vir *Ecklonia maxima*, jodium of enige van die ander bestanddele van **DERMIKELP® ITCH RELIEF LOTION** is (kyk WAT **DERMIKELP® ITCH RELIEF LOTION BEVAT**). Neem spesiale sorg met **DERMIKELP® ITCH RELIEF LOTION**: Indien jou vel stukken is. **DERMIKELP® ITCH RELIEF LOTION** mag 'n brand- of steeksensasie veroorsaak wanneer dit aangewend word op plekke waar die vel stukkend is.

Swangerskap en borsvoedig:
Indien jy swanger is of borsvoed, konsulteer asseblief jou dokter, apteker of gesondheidsorgdeskundige voordat jy **DERMIKELP® ITCH RELIEF LOTION** gebruik. Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

Bestuur en die gebruik van masjinerie:
Geen studies is uitgevoer om die veiligheid van **DERMIKELP® ITCH RELIEF LOTION** te bepaal terwyl 'n voertuig bestuur of masjinerie hanteer word nie. Moenie 'n voertuig bestuur, masjinerie hanteer of enigiets anders doen wat jou aandag vereis totdat jy weet hoe **DERMIKELP® ITCH RELIEF LOTION** jou beïnvloed nie.

Die gebruik van ander medisynes saam met DERMIKELP® ITCH RELIEF LOTION:
Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem (dit sluit komplementêre of tradisionele medisynes in). Moet nie **DERMIKELP® ITCH RELIEF LOTION** in kombinasie met ander topikale toedienings (soos sjampoe, rome of salwe) gebruik nie, behalwe indien anders aangedui deur jou gesondheidsorgdeskundige.

4. HOE OM DERMIKELP® ITCH RELIEF LOTION TE GEBRUIK
Slegs vir uitwendige gebruik. Gebruik altyd **DERMIKELP® ITCH RELIEF LOTION** presies volgens die aanwysings. Kontroleer met jou dokter of apteker indien jy onseker is. Wend aan die aangetaste oppervlak, soos nodig. Masseer sagkens -in die vel in, om te verseker dat dit voldoende geabsorbeer word. **DERMIKELP® ITCH RELIEF LOTION** kan daagliks gebruik word, soos nodig. Indien jy die gevoel kry dat dit effek van **DERMIKELP® ITCH RELIEF LOTION** te sterk of te swak is, bespreek dit met jou dokter of apteker.

Indien jy meer DERMIKELP® ITCH RELIEF LOTION gebruik as wat jy behoort:
Indien jy of jou kind per ongeluk **DERMIKELP® ITCH RELIEF LOTION** ingeneem het, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie inligtingsblad en die oorblywende vloeiroom saam met jou sodat die dokter kan weet wat jy geneem het.
Indien jy vergeet om DERMIKELP® ITCH RELIEF LOTION te gebruik:
Wend daagliks aan, soos nodig.

5. MOONTLIKE NEWE-EFFEKTE
DERMIKELP® ITCH RELIEF LOTION kan newe-effekte hê.
Nie alle newe-effekte wat vir DERMIKELP® ITCH RELIEF LOTION aangemeld is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of indien jy enige ongunstige effekte ervaar terwyl DERMIKELP® ITCH RELIEF LOTION gebruik word, konsulteer asseblief jou dokter, apteker of ander gesondheidsorgdeskundige.

Indien enige van die volgende gebeur, hou op om **DERMIKELP® ITCH RELIEF LOTION** te neem en sê onmiddellik vir jou dokter of gaan of gaan na die ongevalle-afdeling by jou naaste hospital:
- Swelling van jou hande, voete, enkels, gesig, mond of keel, wat probleme met sluk en asemhaling kan veroorsaak.
- Uitslag of gejeuk.
- Floutes.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op **DERMIKELP® ITCH RELIEF LOTION** gehad het. Jy mag dringende mediese aandag of hospitalisasie nodig hê. Sê vir jou dokter indien jy enige van die volgende opmerk:
- Indien jou vel effens rooi word.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genome word nie, lig asseblief jou dokter of apteker in.

6. BERGING EN WEGDOENING VAN DERMIKELP® ITCH RELIEF LOTION
- Bêre by of onder 25 °C.
- Hou buisie dig toe. Beskerm teen direkte sonlig.

BÊRE ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
Moet nie gebruik nả die vervaldatum wat op die etiket of karton voorkom nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

7. AANBIEDING VAN DERMIKELP® ITCH RELIEF LOTION
Wit plastiek bottel in 'n buitenste karton.
Verpakkings groottes: 100 ml, 200 ml.

8. IDENTIFIKASIE VAN DERMIKELP® ITCH RELIEF LOTION
Naaswit tot beige room met 'n kenmerkende geur.

9. REGISTRASIENOMMER
Sal deur die SAHPRA toegeken word.

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
Lamicare SA (Pty) Ltd t/a Lamicare Health
A2, Arden Grove Business Park
Racecourse Road, Milnerton, 7441
Tel: 086 100 0400

11. DATUM VAN PUBLIKASIE
Maart 2020

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-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 substance 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 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, kaprilieglikol, Cananga odorata (ylang-ylang) blomolie, setearielalkohol, setearielglukosied, sitroensuur, etielheksielgliserien, glukonolaktoon, isopropielmiristaat, mineraalolie, PEG-20 stearaat, fenoksiëtanol, natriumbensoaat.

FARMAKOLOGIESE KLASSIFIKASIE
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 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. Fukoïdance in *Ecklonia maxima* verminder die produksie van IgE sowel as dier aantal selle wat IgE afskei in perifere bloed mononukleêere 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-flammatoriese 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 LOTION 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. Geskik vir die vermening van dermatologiese produkte.

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

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
'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.

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

SWANGERSKAP EN BORSVOEDING
Veiligheid tydensswangerskap 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.

INDENTIFIKASIE
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 VOUBILJET
Maart 2020

DKIRL0100-PI/PIL-ZA20
Pro-Print

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THE PROFESSIONALS IN PRINT

REPRO

Date:	29th September 2020
Operator:	Mariette de Bruyn
Customer:	Lamicare
Product Name:	Dermikelp Itch Relief Lotion PI/PIL
Product Code:	DKIRL0100-PI/PIL-ZA20
Dimensions:	210 x 290 mm
Fold Size:	105 x 37 mm
Colours: (1)	Black
	--
	--
Barcode:	--
Pharmacode:	(Ref.20) 1010
Stock:	50 gsm
Proof Status:	3rd (Third)
Proof read by:	

Reset: ☐ **Alterations:** ☐ **Disk/Possie:** ☑

No alterations – proceed as soon as possible ☐

Note alterations – Further proof is required ☐

PLEASE CHECK CAREFULLY.

Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

Signature: ....**Date:** ....

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