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 CREAM

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 CREAM** 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 CREAM CONTAINS

Each gram contains 375 mg of *Ecklonia maxima* (sea kelp) as active substance.
The other ingredients are 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 and water (aqua).

2. WHAT DERMIKELP® ITCH RELIEF CREAM IS USED FOR

DERMIKELP® ITCH RELIEF CREAM soothes itchy irritated skin and is suitable for the symptoms associated with eczema (dry, inflamed, irritated skin), contact dermatitis (skin rash after touching something), seborrhoeic dermatitis (scaling skin rash), minor insect bites and allergic skin reactions caused by soaps, detergents, cosmetics and jewellery.

3. BEFORE YOU USE DERMIKELP® ITCH RELIEF CREAM

Do not use DERMIKELP® ITCH RELIEF CREAM:
If you are hypersensitive (allergic) to *Ecklonia maxima*, iodine or any of the other ingredients of **DERMIKELP® ITCH RELIEF CREAM** (see **WHAT DERMIKELP® ITCH RELIEF CREAM CONTAINS**).

Take special care with DERMIKELP® ITCH RELIEF CREAM:
If you have broken skin areas. **DERMIKELP® ITCH RELIEF CREAM** 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 CREAM**.
Safety during pregnancy and breastfeeding has not been established.

Driving and using machinery:
No studies have been done to establish the safety of **DERMIKELP® ITCH RELIEF CREAM** 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 CREAM** affects you.

Using other medicines with DERMIKELP® ITCH RELIEF CREAM:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).
Do not use **DERMIKELP® ITCH RELIEF CREAM** 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 CREAM

For external use only.
Always use **DERMIKELP® ITCH RELIEF CREAM** 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 CREAM can be used daily as required.
If you have the impression that the effect of **DERMIKELP® ITCH RELIEF CREAM** is too strong or too weak, talk to your doctor or pharmacist.

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

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

5. POSSIBLE SIDE EFFECTS

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

If any of the following happens, stop using **DERMIKELP® ITCH RELIEF CREAM** 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.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **DERMIKELP® ITCH RELIEF CREAM**. 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 CREAM
- Store at or below 25 °C.
- Protect from sunlight.
- Keep container tightly closed.
- Do not remove from outer carton until required for use.
- **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 CREAM

White, plastic tube/jar packed into an outside carton.
Pack sizes: 25 g, 50 g, 100 g and 500 g.

8. IDENTIFICATION OF DERMIKELP® ITCH RELIEF CREAM

Off-white to beige cream with characteristic odour.

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

August 2019

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 CREAM – JEUKVERLIGTENDE ROOM

Lees asseblief hierdie hele inligtingsblad aandagtig 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 CREAM** 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 CREAM BEVAT

Elke gram bevat 375 mg *Ecklonia maxima* (seewier) as aktiewe bestanddeel.
Die ander bestanddele is bensielbensoaat, *Cananga odorata* (ylang-ylang) blomolie, etielheksielgliserien, fenoksiëtanol, glukonolaktoon, isopropielmiristaat, kaprilielglikol, linalool, mineraalolie, natriumbensoaat, PEG-20 stearaat, setearielalkohol, setearielglukosied, sitroensuur en water.

2. WAARVOOR DERMIKELP® ITCH RELIEF CREAM GEBRUIK WORD

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.

3. VOORDAT JY DERMIKELP® ITCH RELIEF CREAM GEBRUIK

Moet nie DERMIKELP® ITCH RELIEF CREAM gebruik nie:
Indien jy hipersensitief (allergies) vir *Ecklonia maxima*, jodium of enige van die ander bestanddele van **DERMIKELP® ITCH RELIEF CREAM** is (kyk **WAT DERMIKELP® ITCH RELIEF CREAM BEVAT**).

Neem spesiale sorg met DERMIKELP® ITCH RELIEF CREAM:
Indien jou vel stukkend is. **DERMIKELP® ITCH RELIEF CREAM** mag 'n brand- of steeksensasie veroorsaak wanneer dit aangewend word op plekke waar die vel stukkend is.

Swangerskap en borsvoeding:
Indien jy swanger is of borsvoed, konsulteer asseblief jou dokter, apteker of gesondheidsorgdeskundige voordat jy **DERMIKELP® ITCH RELIEF CREAM** 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 CREAM** 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 CREAM** jou beïnvloed nie.

Die gebruik van ander medisynes saam met DERMIKELP® ITCH RELIEF CREAM:
Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem (dit sluit komplementêre of tradisionele medisynes in).
Moet nie **DERMIKELP® ITCH RELIEF CREAM** 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 CREAM TE GEBRUIK

Slegs vir uitwendige gebruik.
Gebruik altyd **DERMIKELP® ITCH RELIEF CREAM** 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 CREAM kan daagliks gebruik word, soos nodig.
Indien jy die gevoel kry dat die effek van **DERMIKELP® ITCH RELIEF CREAM** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer DERMIKELP® ITCH RELIEF CREAM gebruik as wat jy behoort:
Indien jy of jou kind per ongeluk **DERMIKELP® ITCH RELIEF CREAM** 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 room saam met jou sodat die dokter kan weet wat jy geneem het.

Indien jy vergeet om DERMIKELP® ITCH RELIEF CREAM te gebruik:
Wend daagliks aan, soos nodig.

5. MOONTLIKE NEWE-EFFEKTE

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

Indien enige van die volgende gebeur, hou op om **DERMIKELP® ITCH RELIEF CREAM** te neem en sê onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- 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 CREAM** gehad het. Jy mag dringende mediese bystand 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 genoem word nie, lig asseblief jou dokter of apteker in.

6. BERGING EN WEGDOENING VAN DERMIKELP® ITCH RELIEF CREAM
- Bêre by of onder 25 °C.
- Beskerm teen direkte sonlig.
- Hou buisie/potjie dig toe.
- **BÊRE ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.**
- Moenie gebruik ná die vervaldatum wat op die etiket of karton voorkom nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

7. AANBIEDING VAN DERMIKELP® ITCH RELIEF CREAM

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

8. IDENTIFIKASIE VAN DERMIKELP® ITCH RELIEF CREAM

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

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