

## 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® OINTMENT

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® OINTMENT** 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® OINTMENT CONTAINS

Each gram contains 75 mg of *Ecklonia maxima* (sea kelp) as active substance. The inactive ingredients are aqua (water), *Cananga odorata* flower oil, caprylyl glycol, cetareth-20, cetearyl alcohol, citric acid, gluconolactone, kaolin, lanolin, petrolatum, phenoxethanol, sodium benzoate, sodium hydroxide, steareth-2 and zinc oxide.

#### 2. WHAT DERMIKELP® OINTMENT IS USED FOR

**DERMIKELP® OINTMENT** soothes itchy irritated skin and is suitable for the symptoms associated with dry eczema, dry contact dermatitis, dry seborrheic dermatitis, and dry skin rashes.

#### 3. BEFORE YOU USE DERMIKELP® OINTMENT

##### Do not use **DERMIKELP® OINTMENT**:

If you are hypersensitive (allergic) to *Ecklonia maxima*, iodine or any of the other ingredients of **DERMIKELP® OINTMENT** (see **WHAT DERMIKELP® OINTMENT CONTAINS**).

##### Take special care with **DERMIKELP® OINTMENT**:

If you have broken skin areas, **DERMIKELP® OINTMENT** 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® OINTMENT**. Safety during pregnancy and breastfeeding has not been established.

##### Driving and using machinery:

No studies have been done to establish the safety of **DERMIKELP® OINTMENT** during driving a vehicle or operating machinery. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how **DERMIKELP® OINTMENT** affects you.

##### Using other medicines with **DERMIKELP® OINTMENT**:

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

#### 4. HOW TO USE DERMIKELP® OINTMENT

For external use only.

Always use **DERMIKELP® OINTMENT** 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® OINTMENT** can be used daily as required.

If you have the impression that the effect of **DERMIKELP® OINTMENT** is too strong or too weak, talk to your doctor or pharmacist.

##### If you use more **DERMIKELP® OINTMENT** than you should:

If you or your child accidentally ingested **DERMIKELP® OINTMENT**, 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 ointment with you so the doctor will know what you have taken.

##### If you forget to use **DERMIKELP® OINTMENT**:

Apply daily as required.

#### 5. POSSIBLE SIDE EFFECTS

**DERMIKELP® OINTMENT** can have side effects.

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

If any of the following happens, stop using **DERMIKELP® OINTMENT** 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® OINTMENT**. 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® OINTMENT

- Store at or below 25 °C.
- Protect from sunlight.
- Keep container tightly closed.
- **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® OINTMENT

White, plastic tube packed into an outside carton.  
Pack sizes: 25 g

#### 8. IDENTIFICATION OF DERMIKELP® OINTMENT

Off-white to beige ointment 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

July 2019

## KOMPLEMENTÊRE MEDISYNE

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

**SKEDULERINGSSTATUS:** S0

### HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM DERMIKELP® OINTMENT - SALF

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® OINTMENT** 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® OINTMENT BEVAT

Die aktiewe bestanddeel is *Ecklonia maxima* (seewier)

Die ander bestanddele is *Cananga odorata* blomolie, fenoksiëtanol, glukonolaktoon, kaolien, kapriliëlglikol, lanolien, natriumbensoaat, natriumhidroksied, petrolatum, seteariet-20, seteariëlkohol, sinkoksied, sitroensuur, stearet-2 en water.

#### 2. WAARVOOR DERMIKELP® OINTMENT GEBRUIK WORD

**DERMIKELP® OINTMENT** streel jeukende, geïrriteerde vel streel en dit is geskik vir die simptome geassosieer met droë ekseem, droë kontakdermatitis, droë seborree-dermatitis, en droë allergiese velreaksies.

#### 3. VOORDAT JY DERMIKELP® OINTMENT GEBRUIK

**Moet nie **DERMIKELP® OINTMENT** gebruik nie:**

Indien jy hipersensitief (allergies) vir *Ecklonia maxima*, jodium of enige van die ander bestanddele van **DERMIKELP® OINTMENT** is (kyk **WAT DERMIKELP® OINTMENT BEVAT**).

##### Neem spesiale sorg met **DERMIKELP® OINTMENT**:

Indien jou vel stukkend is, **DERMIKELP® OINTMENT** 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® OINTMENT** gebruik. Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

##### Bestuur en die gebruik van masjinerie:

Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem (dit sluit komplementêre of tradisionele medisyne in). Moenie **DERMIKELP® OINTMENT** in kombinasie met ander topikale toedienings (soos sjampoe, room of salwe) gebruik nie, behalwe indien anders aangedui deur jou gesondheidsorgdeskundige.

#### 4. HOE OM DERMIKELP® OINTMENT TE GEBRUIK

Slegs vir uitwendige gebruik.

Gebruik altyd **DERMIKELP® OINTMENT** 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® OINTMENT** kan daaglik gebruik word, soos nodig.

Indien jy die gevoel kry dat die effek van **DERMIKELP® OINTMENT** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer **DERMIKELP® OINTMENT** gebruik as wat jy behoort:

Indien jy of jou kind per ongeluk **DERMIKELP® OINTMENT** 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® OINTMENT** te gebruik:

Wend daaglik aan, soos nodig.

#### 5. MOONTLIKE NEWE-EFFEKTE

**DERMIKELP® OINTMENT** kan nuwe-effekte hê.

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

Indien enige van die volgende gebeur, hou op om **DERMIKELP® OINTMENT** te gebruik 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 nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op **DERMIKELP® OINTMENT** 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 nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

#### 6. BERGING EN WEGDOENING VAN DERMIKELP® OINTMENT

Bêre by of onder 25 °C.

Beskerm teen direkte sonlig.

Hou buisie/potjie dig toe.

**BÊRE ALLE MEDISYNE BUIE 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® OINTMENT

Wit plastiekbus verpak in 'n buitenste karton.

Verpakkingsgroottes: 25 g

#### 8. IDENTIFIKASIE VAN DERMIKELP® OINTMENT

Naaswit tot beige salf met 'n kenmerkende geur.

#### 9. REGISTRASIENOMMER

Sal deur die SAHPRA toegeken word.

#### 10. NAAM EN ADRES VAN DIE REGISTRASIEHOUDER

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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