

## COMPLEMENTARY MEDICINE

This unregistered medicine has not been evaluated by the Medicines Control Council for its quality safety or intended use.

### SCHEDULING STATUS S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM  
DERMIKELP® SKIN SPRAY

#### COMPOSITION

##### Active ingredient:

Each ml contains 220.7 mg of *Ecklonia maxima* (Sea Kelp).

##### Inactive ingredients:

Ethyl alcohol, C12-15 Alkyl Benzoate, glycerine, euxyl PE9010, *Cananga odorata* (ylang-ylang).

#### 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 utilized for therapeutic applications as they exhibit antioxidant and anti-inflammatory activities.

#### INDICATIONS

DERMIKELP® SKIN SPRAY assists in soothing itchy and irritated skin, also associated with eczema, psoriasis and dermatitis.

#### CONTRAINDICATIONS

Hypersensitivity to *Ecklonia maxima*, iodine or any of the other ingredients in DERMICELP® SKIN SPRAY (see COMPOSITION).

#### WARNINGS AND SPECIAL PRECAUTIONS

##### FOR EXTERNAL USE ONLY.

Keep the mouth and eyes closed during spraying. Avoid contact with mucosa and eyes.

Avoid application to broken skin. A temporary stinging sensation may be experienced if applied to broken skin.

Spray brief puffs without prolonged spraying.

##### Effects on ability to drive and use machines:

The effect of DERMICELP® SKIN SPRAY on the ability to drive a vehicle and use machines has not been studied.

#### INTERACTIONS

Do not use in combination with other topical skin 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.

Shake well before use.

Hold 15 cm from body and spray onto the affected area. Repeat as required.

Rinse thoroughly with water if DERMICELP® SKIN SPRAY gets into the eyes.

#### SIDE EFFECTS

##### Skin and subcutaneous tissue disorders:

Less frequent: Light erythema.

#### KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

DERMICELP® SKIN SPRAY is indicated for external use only. In the event of accidental ingestion, treatment should be symptomatic and supportive.

#### IDENTIFICATION

Off-white to beige liquid with a characteristic odour.

#### PRESENTATION

A white plastic bottle with mist spray pump, packed into a printed outer carton.  
Pack size: 100 ml.

#### STORAGE INSTRUCTIONS

Store at or below 25 °C.

Protect from sunlight.

#### 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

Registration no: 2008/024158/07

Unit A2, Arden Grove Business Park

Racecourse Road

Milnerton

7441

Tel: 086 100 0400

#### DATE OF PUBLICATION OF PACKAGE INSERT

October 2017

## KOMPLEMENTÈRE MEDISYNE

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

### SKEDULERINGSTATUS S0

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM  
DERMIKELP® VELSPROEI



#### SAMESTELLING

##### Aktiewe bestanddeel:

Elke ml bevat 220.7 mg *Ecklonia maxima* (Seewier).

##### Onaktiewe bestanddele:

Etielalkohol, C12-15 Alkiel Benzoate, glycerine, euxyl PE9010, *Cananga odorata* (ylang-ylang).

#### FARMAKOLOGIESE KLASIFIKASIE

D 33.8 Komplementêre medisyne: Middels met dissiplinespesifieke 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 rol speel.

Floroglucinol, ekkol, 7-floroekkol en 2-floroekkol word uit *Ecklonia maxima* geïsoleer.

##### Farmakinetiese eienskappe:

Die genus *Ecklonia* word vir terapeutiese toedienings benut, aangesien dit antioksidant en anti-inflammatoire werking toon.

#### INDIKASIES

DERMIKELP® VELSPROEI help om jeukende en geirriteerde vel, wat ook geassosieer word met eksem, psoriase en dermatitis, te streef.

#### KONTRA-INDIKASIES

Hipersensitiviteit vir *Ecklonia maxima*, jodium of enige van die ander bestanddele in DERMICELP® VELSPROEI (kyk SAMESTELLING).

#### WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS

##### SLEGS VIR UITWENDIGE GEBRUIK.

Hou die mond en oë toe terwyl gespuit word. Vermy kontak met slymvliese en oë.

Vermy toediening aan stukkende vel. 'n Tydelike brandende sensasie mag gevoel word indien dit aan stukkende vel aangewend word.

Spuit kort sproeie, vermy lang bespuiting.

#### Uitwerking op die vermoë om te bestuur en masjienerie te gebruik:

Die effek van DERMICELP® VELSPROEI op die vermoë om 'n voertuig te bestuur en masjiene te gebruik, is nie bestudeer nie.

#### INTERAKSIES

Moet nie in kombinasie met ander topikale velprodukte 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.

Skud goed voor gebruik.

Hou 15 cm van die liggaaam en spuit op die aangetaste area. Herhaal soos nodig.

Spoel deeglik met water indien DERMICELP® VELSPROEI in die oë kom.

#### NEWE-EFFEKTE

##### Vel- en subkutaneweefselversteurings:

Minder dikwels: Lige eritem.

#### BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN

DERMICELP® VELSPROEI word slegs vir uitwendige gebruik aangedui. In die geval van toevallige inname, moet behandeling simptomaties en ondersteunend wees.

#### IDENTIFIKASIE

Naaswit tot roomkleurige vloeistof met 'n kenmerkende reuk.

#### AANBIEDING

'n Wit plastiese bottel met mis sproeipomp, verpak in gedrukte buitenste karton.

Verpakkingsgrootte: 100 ml.

#### BEWARINGSINSTRUKSIES

Bére by of onder 25 °C.

Beskerm teen direkte sonlig.

#### 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

Registration no: 2008/024158/07

Unit A2, Arden Grove Business Park

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#### DATUM VAN PUBLIKASIE VAN DIE VOUBLIJET

Oktober 2017