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

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM
BITE & STING™ RELIEF CREAM

COMPOSITION
Active ingredient:
Each gram contains 375 mg of *Ecklonia maxima* (sea kelp).
Inactive ingredients:
Aqua, Isopropyl Myristate, Cetearyl Alcohol, White Soft Paraffin, PEG-20 Stearate, Phenoxyethanol, Cetearyl Glucoside, Citronella (*Cymbopogon Nardus)* Oil, Polysorbate 20, Gluconolactone, Phenoxyethanol, Sodium Benzoate, Caprylyl Glycol, Citric Acid, Ethylhexylglycerin

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
BITE & STING™ RELIEF CREAM is clinically proven to soothe itchy irritated skin and is suitable for minor insect bites, stings and stinging nettles.

CONTRAINDICATIONS
Hypersensitivity to *Ecklonia maxima*, iodine or any of the other ingredients in **BITE & STING™ 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
Printed, plastic tube/jar packed into an outside carton.
Pack sizes: 7 g & 25 g

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 SAHPRA.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Lamicare SA (Pty) Ltd
A2, Arden Grove Business Park
Racecourse Road
Milnerton
7441
Tel: 086 100 0400

DATE OF PUBLICATION OF PACKAGE INSERT
December 2019

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

SKEDULERINGSTATUS: S0

HANDELSNAAM EN DOSEERVORM
BITE & STING™ VERLIGTINGDE ROOM

SAMESTELLING
Aktiewe bestanddeel:
Elke gram bevat 375 mg *Ecklonia maxima* (seewier)
Onaktiewe bestanddele:
Aqua, Isopropyl Myristate, Cetearyl Alcohol, White Soft Paraffin, PEG-20 stearate, Phenoxyethanol, Cetearyl Glucoside, Citronella (*Cymbopogon Nardus)* Oil, Polysorbate 20, Gluconolactone, Phenoxyethanol, Sodium Benzoate, Caprylyl Glycol, Citric Acid, Ethylhexylglycerin

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
Dit is klinies bewys dat **BITE & STING™ VERLIGTENDE ROOM** jeukende, geïrriteerde vel streel. Dit is geskik vir die simptome geassosieer met insekbyte, steke en brandnetels.
KONTRA-INDIKASIES
Hipersensitiwiteit vir *Ecklonia maxima*, jodium of enige van die ander bestanddele in **BITE & STING™ VERLIGTENDE ROOM** (kyk **SAMESTELLING**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
'n Tydelik steeksensasie mag gevoel word wanneer **BITE & STING™ VERLIGTENDE ROOM** 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
Gedrukte plastiekbuis/potjie verpak in 'n buitenste karton.
Verpakkingsgroottes: 7 g, 25 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 SAHPRA toegeken word.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
Lamicare SA (Edms) Bpk
A2, Arden Grove Business Park
Racecourse Road
Milnerton
7441
Tel: 086 100 0400

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET
Desember 2019

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

SCHEDULING STATUS: S0

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
BITE & STING™ 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 **BITE & STING™ 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 BITE & STING™ RELIEF CREAM IS**
Each gram contains 375 mg of *Ecklonia maxima* (Sea Kelp) as active substance.
Inactive substances: Aqua, Isopropyl Myristate, Cetearyl Alcohol, White Soft Paraffin, PEG-20 Stearate, Phenoxyethanol, Cetearyl Glucoside, Citronella (*Cymbopogon Nardus*) Oil, Polysorbate 20, Gluconolactone, Phenoxyethanol, Sodium Benzoate, Caprylyl Glycol, Citric Acid, Ethylhexylglycerin.

2. **WHAT BITE & STING™ RELIEF CREAM IS USED FOR**
BITE & STING™ RELIEF CREAM is clinically proven to soothe itchy irritated skin and is suitable for minor insect bites, stings and stinging nettles.

3. **BEFORE YOU USE BITE & STING™ RELIEF CREAM**
Do not use BITE & STING™ RELIEF CREAM:
If you are hypersensitive (allergic) to *Ecklonia maxima*, iodine or any of the other ingredients of **BITE & STING™ RELIEF CREAM** (see **BITE & STING™ RELIEF CREAM CONTAINS).**
Take special care with BITE & STING™ RELIEF CREAM:
If you have broken skin areas. **BITE & STING™ 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 **BITE & STING™ 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 **BITE & STING™ 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 **BITE & STING™ RELIEF CREAM** affects you.

Using other medicines with BITE & STING™ RELIEF CREAM:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).
Do not use **BITE & STING™ RELIEF CREAM** in combination with other topical applications (such as creams or ointments) unless otherwise indicated by your healthcare professional.

4. **HOW TO USE BITE & STING™ RELIEF CREAM**
For external use only.
Always use **BITE & STING™ 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.
BITE & STING™ RELIEF CREAM can be used daily as required.
If you have the impression that the effect of **BITE & STING™ RELIEF CREAM** is too strong or too weak, talk to your doctor or pharmacist.

If you use more BITE & STING™ RELIEF CREAM than you should:
If you or your child accidentally ingested **BITE & STING™ 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 BITE & STING™ RELIEF CREAM:
Apply daily as required.

5. **POSSIBLE SIDE EFFECTS**
BITE & STING™ RELIEF CREAM can have side effects.
Not all side effects reported for BITE & STING™ RELIEF CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using BITE & STING™ RELIEF CREAM, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using **BITE & STING™ 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 **BITE & STING™ 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 BITE & STING™ RELIEF CREAM**
Store at or below 25 °C.
Keep closed. Protect from sunlight.
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 BITE & STING™ RELIEF CREAM**
Printed, plastic tube/jar packed into an outside carton.
Pack sizes: 7 g, 25 g

8. **IDENTIFICATION OF BITE & STING™ RELIEF CREAM**
Off-white to beige cream with characteristic odour.

9. **REGISTRATION NUMBER**
To be allocated by SAHPRA.

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

11. **DATE OF PUBLICATION**
December 2019

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

SKEDULERINGSTATUS: S0

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
BITE & STING™ VERLIGTINGDE ROOM

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 **BITE & STING™ VERLIGTINGDE ROOM** 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 BITE & STING™ VERLIGTINGDE ROOM BEVAT**
Die aktiewe bestanddeel is *Ecklonia maxima* (Seewier).
Inaktiewe bestanddele: Aqua, Isopropyl Myristate, Cetearyl Alcohol, White Soft Paraffin, PEG-20 Stearate, Phenoxyethanol, Cetearyl Glucoside, Citronella (*Cymbopogon Nardus*) Oil, Polysorbate 20, Gluconolactone, Phenoxyethanol, Sodium Benzoate, Caprylyl Glycol, Citric Acid, Ethylhexylglycerin

2. **WAARVOOR BITE & STING™ VERLIGTINGDE ROOM GEBRUIK WORD**
Dit is klinies bewys dat **BITE & STING™ VERLIGTINGDE ROOM** jeukende, geïrriteerde vel streel. Dit is geskik vir die simptome geassosieer met insekbyte, steke en brandnetels.

3. **VOORDAT JY BITE & STING™ VERLIGTINGDE ROOM GEBRUIK**
Moet nie BITE & STING™ VERLIGTINGDE ROOM gebruik nie:
Indien jy hipersensitief (allergies) vir *Ecklonia maxima*, jodium of enige van die ander bestanddele van **BITE & STING™ VERLIGTINGDE ROOM VEL** is (kyk **BITE & STING™ VERLIGTINGDE ROOM BEVAT**).
Neem spesiale sorg met BITE & STING™ VERLIGTINGDE ROOM:
Indien jou vel stukkend is. **BITE & STING™ VERLIGTINGDE ROOM** 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 **BITE & STING™ VERLIGTINGDE ROOM** gebruik.
Veiligheid tydens swangerskap en borsvoeding is nie bepaal nie.

Bestuur en die gebruik van masjinerie:
Geen studies is uitgevoer om die veiligheid van **BITE & STING™ VERLIGTINGDE ROOM** 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 **BITE & STING™ VERLIGTINGDE ROOM** jou beïnvloed nie.

Die gebruik van ander medisynes saam met BITE & STING™ VERLIGTINGDE ROOM:
Sê altyd vir jou gesondheidsorgdeskundige indien jy enige ander medisyne neem (dit sluit komplementêre of tradisionele medisynes in).
Moet nie **BITE & STING™ VERLIGTINGDE ROOM** in kombinasie met ander topikale toedienings (soos sjampoe, rome of salwe) gebruik nie, behalwe indien anders aangedui deur jou gesondheidsorgdeskundige.

4. **HOE OM BITE & STING™ VERLIGTINGDE ROOM TE GEBRUIK**
Slegs vir uitwendige gebruik.
Gebruik altyd **BITE & STING™ VERLIGTINGDE ROOM** 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.
BITE & STING™ VERLIGTINGDE ROOM kan daagliks gebruik word, soos nodig.
Indien jy die gevoel kry dat die effek van **BITE & STING™ VERLIGTINGDE ROOM** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer BITE & STING™ VERLIGTINGDE ROOM gebruik as wat jy behoort:
Indien jy of jou kind per ongeluk **BITE & STING™ VERLIGTINGDE ROOM** 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 BITE & STING™ VERLIGTINGDE ROOM te gebruik:
Wend daagliks aan, soos nodig.

5. **MOONTLIKE NEWE-EFFEKTE**
BITE & STING™ VERLIGTINGDE ROOM kan newe-effekte hê.
Nie alle newe-effekte wat vir BITE & STING™ VERLIGTINGDE ROOM aangemeld is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of indien jy enige ongunstige effekte ervaar terwyl BITE & STING™ VERLIGTINGDE ROOM gebruik word, konsulteer asseblief jou dokter, apteker of ander gesondheidsorgdeskundige.

Indien enige van die volgende gebeur, hou op om **BITE & STING™ VERLIGTINGDE ROOM** 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 **BITE & STING™ VERLIGTINGDE ROOM** 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 genoem word nie, lig asseblief jou dokter of apteker in.

6. **BERGING EN WEGDOENING VAN BITE & STING™ VERLIGTINGDE ROOM**
Bêre by of onder 25 °C.
Beskerm teen direkte sonlig.
Hou buisie dig toe.
BÊRE ALLE MEDISYNE BUITE DIE BEREIK VAN KINDERS.
Moet nie gebruik ná 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 BITE & STING™ VERLIGTINGDE ROOM**
Gedrukte plastiekbuis/potjie verpak in 'n buitenste karton.
Verpakkingsgroottes: 7 g, 25 g

8. **IDENTIFIKASIE VAN BITE & STING™ VERLIGTINGDE ROOM**
Naaswit tot beige room met 'n kenmerkende geur.

9. **REGISTRASIENOMMER**
Sal deur SAHPRA toegeken word.

10. **NAAM EN ADRES VAN DIE REGISTRASIEHOUER**
Lamicare SA (Edms) Bpk
A2, Arden Grove Business Park
Racecourse Road, Milnerton, 7441
Tel: 086 100 0400

11. **DATUM VAN PUBLIKASIE**
Desember 2019

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