

SCHEDULING STATUS: **S0**

## DERMAMEND Cream

Zinc oxide / Rose Geranium oil

### COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

### Read all of this leaflet carefully because it contains important information for you.

DERMAMEND is available without a doctor's prescription. Nevertheless, you still need to use DERMAMEND carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your or your child's symptoms worsen or do not improve after 7 days.

### What is in this leaflet

1. What DERMAMEND is and what it is used for.
2. What you need to know before you use DERMAMEND.
3. How to use DERMAMEND.
4. Possible side effects.
5. How to store DERMAMEND.
6. Contents of the pack and other information.

#### 1. What DERMAMEND is and what it is used for

DERMAMEND is a skin cream that can support skin health and improve internal skin structure. This may support maintenance of skin allergies, acne, diaper rash and cracked lips, heels and elbows.

#### 2. What you need to know before you use DERMAMEND

##### Do not use DERMAMEND:

- If you or your child are hypersensitive (allergic) to any of the ingredients of DERMAMEND (listed in section 6).
- On open wounds or hypersensitive skin.

### Warnings and precautions

#### Take special care with DERMAMEND:

Avoid contact with your eyes. If contact occurs, rinse thoroughly with water.

### Other medicines and DERMAMEND

Always tell your healthcare provider if you or your child are taking / using any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you or your child are currently using:

- Steroid cream (used to treat inflamed, itchy or irritated skin).
- Antifungal cream (used to treat fungal infections of the skin, scalp and nails).

### Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using DERMAMEND.

Safety during pregnancy and breastfeeding has not been established. Do not use DERMAMEND if you are pregnant or breastfeeding.

### Driving and using machines

DERMAMEND is unlikely to affect your ability to drive a vehicle and use machines.

#### 3. How to use DERMAMEND

Always use DERMAMEND exactly as described in this leaflet or as your pharmacist have told you. Check with your pharmacist if you are not sure.

##### *Babies, children and adults:*

Apply 3 times a day on affected area.

Massage deep into the skin. Do not apply as a thick layer.

Do not exceed the recommended dosage.

Only for external use.

### If you take more DERMAMEND than you should

If you or your child accidentally ingests DERMAMEND, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the remaining DERMAMEND with you so the doctor will know what you or your child have ingested.

#### 4. Possible side effects

DERMAMEND can have side effects.

Not all side effects reported for DERMAMEND are included in this leaflet.

Should your or your child's general health worsen or if you experience any untoward effects while using DERMAMEND, please consult your healthcare provider for advice.

If any of the following happens, stop taking DERMAMEND and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to DERMAMEND. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

##### *Frequency unknown:*

- Burning or tingling skin sensation, redness of your skin.

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

### Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

<http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of DERMAMEND.

#### 5. How to store DERMAMEND

- Store in a dry place at or below 25 °C.
- Protect from direct sunlight.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

#### 6. Contents of the pack and other information

##### What DERMAMEND contains

Each 1 g cream contains:

Zinc oxide	0,07 g
<i>Pelargonium graveolens</i> L'Hér. (Rose Geranium oil)	0,003 g

The other ingredients are cetearyl alcohol, citric acid, dimethicone, emulsifying wax, glycerine, lanolin, mineral oil, 2-phenoxyethanol, purified water, sorbitan monooleate, tocopheryl acetate and xanthan gum.

##### What DERMAMEND looks like and contents of the pack

A white cream with a distinct rose scent.

DERMAMEND is available in tubs of 50 g and 125 g.

##### Holder of certificate of registration



LOOCK PHARMACEUTICALS (Pty)Ltd

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##### This leaflet was last revised in

October 2022.

##### Registration number

Will be allocated by SAHPRA upon registration.

##### Access to corresponding Professional Information

<https://loockpharmaceuticals.co.za/product-details/dermamend/>

SKEDULERINGSSTATUS: **S0**

## DermaMend Room

Sinkoksied / Roos-Geraniumolie

### KOMPLEMENTÊRE MEDISYNE: GESONDHEIDSAANVULLING

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

### Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.

DERMAMEND is beskikbaar sonder 'n dokter se voorskrif.

Jy moet DERMAMEND nogtans met sorg gebruik om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.
- Jy moet 'n dokter sien as jou of jou kind se simptome vererger of nie verbeter na 7 dae nie.

### Wat is in hierdie inligtingsblad

1. Wat is DERMAMEND en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy DERMAMEND gebruik.
3. Hoe om DERMAMEND te gebruik.
4. Moontlike nuwe-effekte.
5. Hoe om DERMAMEND te bêre.
6. Inhoud van die pak en ander inligting.

#### 1. Wat is DERMAMEND en waarvoor word dit gebruik

DERMAMEND is 'n velroom wat die gesondheid van jou vel kan ondersteun en interne velstruktuur kan verbeter. Dit ondersteun die instandhouding van velallergieë, aknee, doekuitslag en gebarste lippe, hakke en elmoë sluit.

#### 2. Wat jy moet weet voordat jy DERMAMEND neem

##### Moenie DERMAMEND gebruik

- Indien jy of jou kind hipersensitief (allergies) is vir enige van die bestanddele van DERMAMEND (gelys by afdeling 6).
- Op oop wonde of hipersensitiewe vel.

##### Waarskuwings en voorsorgmaatreëls

##### Wees veral versigtig met DERMAMEND:

Vermý kontak met jou oë. Spoel deeglik uit met water indien kontak plaasgevind het.

##### Ander medisyne en DERMAMEND

Sê altyd vir jou gesondheidsorgverskaffer indien jy of jou kind enige ander medisyne neem / gebruik.

(Dit sluit alle komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy of jou kind tans die volgende gebruik:

- Steroïedroom (gebruik om ontsteekte, jeukerige of geïrriteerde vel te behandel).
- Swamwerende salf (word gebruik om swaminfeksies van die vel, kopvel en naels te behandel).

##### Swangerskap, borsvoeding en vrugbaarheid

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy DERMAMEND neem.

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie. Moenie DERMAMEND gebruik indien jy swanger is of jou baba borsvoed nie.

##### Bestuur en die gebruik van masjiene

Dit is onwaarskynlik dat DERMAMEND jou vermoë om 'n voertuig te bestuur en masjiene te gebruik sal belemmer.

#### 3. Hoe om DERMAMEND te neem

Gebruik DERMAMEND altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou apteker vir jou gesê het. Vra gerus jou apteker indien jy onseker is.

##### Babas, kinders en volwassenes:

Wend 3 keer per dag aan op die geaffekteerde area.

Masseer diep in die vel in. Moenie as 'n dik laag toedien nie.

Moenie die aanbevole dosis oorskry nie.

Slegs vir eksterne gebruik.

##### Wat om te doen indien jy meer DERMAMEND geneem het as wat jy moet

Indien jy of jou kind per ongeluk DERMAMEND inneem, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem hierdie pamflet en die oorblywende DERMAMEND saam sodat die dokter sal weet wat jy of jou kind ingeneem het.

#### 4. Moontlike nuwe-effekte

DERMAMEND kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir DERMAMEND gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou of jou kind se algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl DERMAMEND gebruik word, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om DERMAMEND te gebruik en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling;
- uitslag of gejeuk;
- floute.

Hierdie is baie ernstige nuwe-effekte. Indien jy of jou kind enige daarvan ondervind, mag dit wees dat julle 'n ernstige allergiese reaksie op DERMAMEND gehad het. Dringende mediese bystand of hospitalisasie mag benodig word.

Sê vir jou dokter indien jy enige van die volgende opmerk:

##### Onbekende frekwensie:

- Brandende of tintelende velsensasie, rooiheid van jou vel.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

##### Aanmelding van nuwe-effekte

Indien enige nuwe-effekte ondervind word, bespreek dit met jou dokter of apteker.

Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>

Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van DERMAMEND te verskaf.

#### 5. Hoe om DERMAMEND te bêre

- Bêre in 'n droë plek by of onder 25 °C.
- Beskerm teen direkte sonlig.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik na die vervaldatum wat op die verpakking gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioelstelsels (bv. toilette) weggooi nie.

#### 6. Inhoud van die pak en ander inligting

##### Wat DERMAMEND bevat

Elke 1 g room bevat:

Sinkoksied	0,07 g
<i>Pelargonium graveolens</i> L'Hér. (Roos-Geraniumolie)	0,003 g

Die ander bestanddele is setearielalkohol, sitroensuur, dimetikoon, emulsiferende waks, gliserien, lanolien, mineraalolie, 2-fenoksie-etanol, gesuiwerde water, sorbitaan-monoöktanoaat, tokoferielasetaat en xantangom.

##### Hoe DERMAMEND lyk en inhoud van die verpakking

'n Wit room met 'n kenmerkende roosgeur.

DERMAMEND is beskikbaar in houers van 50 g en 125 g.

##### Houer van die Registrasiesertifikaat



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##### Hierdie inligtingsblad is laas hersien in

Oktober 2022.

##### Registrasienommer

Vir toekenning deur SAHPRA met registrasie.

##### Toegang tot die ooreenstemmende Professionele inligtingsblad

<https://loockpharmaceuticals.co.za/product-details/dermamend/>