

Professional Information for DERMAMEND

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE

DERMAMEND cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g cream contains:

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

A white cream with a distinct rose scent.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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.

4.2 Posology and method of administration

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.

4.3 Contraindications

Hypersensitivity to Zinc oxide, Geranium oil or any of the excipients listed in section 2 or 6.1.

Open wounds or hypersensitive skin.

4.4 Special warnings and precautions for use

Eye warning

Patients should avoid contact with their eyes. If contact occurs, rinse thoroughly with water.

Long-term use

Patients should stop use and consult a healthcare provider if symptoms worsen or last for more than 7 days.

4.5 Interaction with other medicines and other forms of interaction

Steroid or antifungal cream

It is advisable that a patient does not apply this cream to an area of the skin which has recently been treated with a potent steroid or antifungal cream, as the skin may be sensitive and side effects may be experienced more easily. It might also affect the absorption and effectivity of other creams.

Patients should avoid applying DERMAMEND in conjunction with any other preparations to ensure that the best results are achieved.

4.6 Fertility, pregnancy and lactation

The safety of DERMAMEND during pregnancy has not been established and therefore it should be avoided.

4.7 Effects on ability to drive and use machines

DERMAMEND is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

DERMAMEND is generally well tolerated.

Immune system disorders:

Frequency unknown: hypersensitivity and/or allergic reactions.

Skin and subcutaneous tissue disorders:

Frequency unknown: skin irritation, burning or tingling skin sensation, redness, rash or itching.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of DERMAMEND is important. It allows continued monitoring of the benefit/risk balance of DERMAMEND. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications:

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

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 34.12 Multiple substance formulation.

DERMAMEND contains Zinc oxide and Rose Geranium oil which may support skin health and improve internal skin structure.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetearyl alcohol,
citric acid,
dimethicone,
emulsifying wax,
glycerine,
lanolin,
mineral oil,
2-phenoxyethanol,
purified water,
sorbitan monooleate,
tocopheryl acetate,
xanthan gum.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store in a dry place at or below 25 °C.

Protect from direct sunlight.

Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION



LOOCK PHARMACEUTICALS (Pty)Ltd

39 Eagles Landing
Rockcliff Estate
Rustenburg
0299

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

October 2022.